HOTLINE 2014-152

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF
INSPECTOR GENERAL

June 6, 2014

MEMORANDUM

SUBJECT: Office of Inspector General Hotline Complaint 2014-152

FROM: [redacted]
Special Agent in Charge
Headquarters, Office of Inspector General

TO: Francesca T. Grifo, Ph.D.
Scientific Integrity Official

The Environmental Protection Agency (EPA), Office of Inspector General (OIG), Hotline received an electronic message from [redacted] contacted the Hotline to request assistance in a retraction of and EPA funded study that he believes in error.

The Hotline is forwarding this as requested in your June 2, 2014, electronic message. Please advise the Hotline if any OIG assistance is needed [redacted] will be informed that his request has been forwarded to your office.

Please inform the Hotline within the next 5 calendar days that this has been received. If you have any further questions, please call Special Agen[redacted], Hotline Program Manager, at 202-566-[redacted]

Attachment:

cc: Carolyn Copper, AIG OPE OIG

[redacted]

From: [redacted]
Sent: Thursday, May 29, 2014 4:54 PM
To: [redacted]
Subject: request for OIG investigation of HEI fraud
Attachments: HEI greenbaum Letter to [redacted]

[redacted]

Thanks for talking with me today about the letter I cc'd to the OIG on May 19 requesting retraction of an approx. $2.5 million study that EPA commissioned from the Health Effects Institute, which has been continuously funded by HEI since 1981 [and currently at the rate of about $17M/year] . Please share this email with whoever is assigned to reads my letter.

The study I'm concerned with was published twice in 1989 [by HEI and the NEJM] and again in 1991at EPA's request by EHP, the official journal of NIEHS. It is still being cited by EPA [as recently as August 2011] as the "primary basis" for the CO NAAQS, on the assumption that its methods and results are valid.

The study has been endorsed by three successive CO CASAC review panels appointed by EPA but all were [redacted]--subsequently dismissed by [redacted]--concerning the failure of [redacted] and SAB staff to disclose this obvious source of potential bias to either this fellow CASAC members or the public.

Assuming the EPA's OIG agrees that the evidence I've compiled documents scientific misconduct on the part of HEI in this study [defined as fabrication, falsification and/or plagiarism], I would like the OIG to consider whether HEI should be sanctioned in some way for this research fraud --even though the statute of limitations for recovering the funds involved has long passed.

Given the study's importance [CO kills and poisons more people in USA annually than any other toxin] and that HEI-affiliated scientists on EPA appointed CASAC panels have promoted the study to EPA as a sound basis for the CO NAAQS since 1991, I think some sanctions are warranted on both HEI and the researchers involved -- if only to send a clear signal to all EPA grantees that scientists caught defrauding the federal government will not be rewarded with further grants or contracts for some number of years if not permanently barred.

At the very least I hope the OIG will instruct HEI to stop throwing away the archives of EPA-funded air pollution studies without first offering them to EPA so staff can preserve those that are still being cited as the basis for EPA regulations (as the Data Quality Act requires). A letter from HEI Exec. Director Dan Greenbaum defending this practice is attached.

HEI's Board of Directors and the journals involved have not yet responded to my letter but I will keep you informed if they do.

The issues I raise also may be of concern to your program review office but only if the inspectors find some merit in my allegations of scientific misconduct.

Thank you for your consideration. I look forward to some reply.

[redacted]

From: Sullivan, Patrick F.
Sent: Monday, May 19, 2014 8:36 PM
To: [redacted]
Cc:
Subject: FW: Retraction request
Attachments: [redacted] letter requesting retraction.doc

Hotline.....
Patrick F. Sullivan
Assistant Inspector General for Investigations
EPA Office of Inspector General
Desk: (202) 566-0308
Cell: (571) 243-2195
Email: sullivan.patrick@epa.gov

From: Elkins, Arthur
Sent: Monday, May 19, 2014 7:26 PM
To: Sullivan, Patrick F.
Cc: Sheehan, Charles; Larsen, Alan
Subject: Fw: Retraction request

Will be pending more info

Patrick,

Please see the below hotline complaint. Please follow-up as appr

Thanks.

Art

[redacted] du>

Sent: Monday, May 19, 2014 5:34:50 PM
To: Mccarthy, Gina; Elkins, Arthur; Grifo, Francesca; Costa, Dan
Subject: Retraction request

The attached letter is cc'd to you. It requests retraction of the Allred et al study of carbon monoxide that was published by the Health Effects Institute (1989), The New England Journal of Medicine (1989), and Environmental Health Perspectives (1991).

My request is based on extensive evidence of misconduct and other significant deviations from the norms of scientific research that I've documented in the letter and seven appendices.

Because EPA commissioned this study from HEI in 1983 and has been citing it as the primary basis for the CO National Ambient Air Quality Standards since 1991, including most recently in 2011, I hope

you will review this evidence and reconsider EPA's faith in both the Alired study and HEI, which directed it.

If you find fault with my reanalysis, please let me know so that I may issue a correction and an apology. But if not--if you agree that this study is not of sufficient quality to be cited as the basis of EPA regulations--I hope EPA will stop citing it except as an example of the type of scientific misconduct for which federal contractors such as HEI should be disbarred. I trust EPA also will ban all the authors, including [redacted] from ever again being appointed to EPA's [redacted] or other any federal advisory committees.

Unlike the last time the evidence basis for the CO NAAQS was cast into doubt--back in the early 1980s when EPA's then most-cited CO researcher, Dr. Aronow, admitted fabricating drug testing data he'd submitted to FDA, I beg EPA not to commission even one more CO study. There are already over 25,000 references on CO in the medical literature that EPA has never reviewed, including over 5,000 published just since the last CO NAAQS review began in 2009.

Thank you for your consideration. I look forward to your reply.

[redacted]

An open letter requesting retraction of all three published versions of the 'Multicenter Carbon Monoxide Study' by the Health Effects Institute's Multicenter CO Study Team (Allred *et al.*)

May 19, 2014

Dr. Jeffrey M. Drazen, Editor-in-Chief, New England Journal of Medicine
Dr. Hugh Tilson, Editor-in-Chief, Environmental Health Perspectives
Health Effects Institute Board of Directors,[1] c/o Dr. Daniel Greenbaum, President

Dear Editors and HEI Directors,

On August 1, 1994, the United States Environmental Protection Agency [EPA] cited your publications of a human exposure study by Allred *et al* (1989a, 1989b and 1991) among the evidence for maintaining the National Ambient Air Quality Standards (NAAQS) for carbon monoxide [CO] at their original 1971 levels.[2] Seventeen years later, on August 31, 2011, EPA's Office of Air and Radiation—then under the direction of Gina McCarthy, the current Administrator—completed its most recent review of the CO NAAQS and again decided to keep the 1971 standards unchanged. This time EPA singled out Allred *et al.* as the one study "given primary consideration in this review" and explicitly gave no weight to epidemiological studies or any other types of evidence.[3]

Allred *et al* (1989b) is also cited as the basis for Health Canada's similar "National Ambient Air Quality Objectives" for CO and by the World Health Organization Regional Office for Europe in its "Air Quality Guidelines for Europe."[4] Other countries with the same CO exposure standard as the US or Canada include Australia, New Zealand, South Africa, the United Kingdom, and most of Europe. Over 750 million people live under these CO standards.

While Allred *et al*—formally known as the Health Effects Institute's Multicenter Carbon Monoxide Study [HEI's MCO study]—is considered a landmark in regulatory toxicology, its design is fundamentally flawed and its conclusions are not supported by its results, some of which appear too good to be true. Ironically, EPA commissioned this study from HEI in 1983 to replicate a smaller but similarly flawed CO study that the agency had commissioned just four years earlier from a cardiologist at the Veterans Administration, Dr. Wilbert Aronow (US GAO 1984).[5]

Dr. Aronow never obtained VA approval for his EPA research, however, nor for other human studies on the safety and efficacy of new cardiac drugs for pharmaceutical companies. (US GAO 1984). The latter came to light in 1979 when Dr. Aronow admitted to the US Food and Drug Administration [FDA] that much of the drug data he had submitted was fabricated (US GAO 1984). The FDA barred him from submitting any more and informed the VA, which ordered him to stop

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[1] This letter is directed to HEI Board of Directors in the absence of an executive editor for its research reports. The board comprises Sharwood Boehlert, Dr. Enriqueta Bond, Richard Celeste (chair), Dr. Purnell Choppin, Dr. Michael Clegg, Dr. Jared Cohon, Stephen Corman, Goolsbee Rizvi, Dr. Linda Rosenstock, Henry Schacht, Dr. Warren Washington, and Dr Donald Kennedy (vice chair emeritus). List accessed 5/5/2014 at http://www.healtheffects.org/board.htm

[2] US EPA. 59 FR 38906, August 1, 1994. The CO NAAQS allows CO exposure outdoors of up to an average of 9 parts per million (ppm) over eight hours and up to 35 ppm average over one hour.

[3] US EPA. 76 FR 54294, August 31, 2011. In contrast, none of EPA's other NAAQS rulemakings—for particulate matter, ozone, nitric dioxide, sulfur dioxide, or lead—have ever given "primary consideration" to any single study.

[4] Allred *et al* cited by Health Canada in www.hc-sc.gc.ca/ewh-semt/pubs/air/naaqo-onqae/carbon-monoxide-carbone/index-eng.php and WHO Regional Office for Europe in www.euro.who.int/__data/assets/pdf_file/0005/74732/E71922.pdf

[5] EPA first cited 7 CO studies by Dr. Aronow, none of which acknowledged any funding source, and one study from EPA's own human exposure lab (Anderson 1973) as the basis for the CO NAAQS in its 1979 Criteria Document. Prior to this and dating back to the adoption of the CO NAAQS in 1971, EPA had based the standard on one study of neurological effects (Beard 1967). When multiple researchers, including EPA staff, were unable to replicate Beard's results (Otto 1979), EPA decided to base the CO NAAQS instead on the effects of CO in men with angina first reported by Dr. Aronow.

doing human research of any kind. Although neither the FDA nor VA alerted the journals that had published Aronow's findings, both informed the EPA of Aronow's misconduct in 1982 (US GAO 1984).

The EPA and its CO Clean Air Scientific Advisory Committee nevertheless continued promoting Dr. Aronow's CO studies as the best available evidence in support of the CO NAAQS. EPA did not stop doing so until the Washington Post published an article about Dr. Aronow's misconduct in March 1983 (Mintz). Within a month, EPA appointed a "special peer review committee" of four university researchers to interview Dr. Aronow and conduct a rigorous data audit of his CO studies (Peterson 1983a, US GAO 1984). Aronow insisted all his results were valid but acknowledged having discarded most of his documentation (Peterson 1983b).

Without the original records needed to reanalyze Dr. Aronow's results, the committee concluded "that EPA cannot rely on Dr. Aronow's data ... We further recommend that EPA encourage additional research efforts to resolve this impasse and that in addition to the [EPA-funded and co-authored] research program presently underway at Chapel Hill, EPA needs to have other independent research groups undertake such investigations. Furthermore, EPA should develop a quality assurance program for COHb similar to the one it has in effect for sulfates" (Horvath 1983 as quoted by Cox 1984). EPA officials met with the Aronow review committee and other researchers at a workshop convened by HEI to discuss possible CO study designs on July 12, 1983. Just 10 days later, EPA commissioned HEI to replicate Aronow's 1981 study.[6]

This came just one month after HEI's Health Research Committee [HRC] had issued a traditional request for investigator-initiated research proposals on cardiac effects of CO exposure. Rather than issue another request, HEI decided to undertake this study itself (Cox 1984, Williams 1985). HEI appointed three of its HRC members and three outside experts—including two of the four who had just investigated Aronow for the EPA—to a 'CO Oversight Committee' [COOC] tasked with organizing the study.[7]

The COOC's name was changed before publication to the 'HEI Advisory Committee' but its members played a much greater role than either name suggests. As the authors acknowledge only in their HEI report, this committee was formed in August 1983 to "assist the HEI in selecting investigators, planning the study, and providing guidance throughout the study" (Allred 1989a).

In fact, the COOC planned the study first and then hired clinical cardiologists to conduct it (Cox 1984, Williams 1985). HEI sent the COOC's multi-center proposal to 271 cardiology departments in September 1983 and hired three teams two months later.

Like Aronow, the HEI study assessed the effect of CO exposures in men with coronary artery disease based on how long they could exercise in fresh air after being exposed to either air or different levels of CO. The primary outcome measures were based on how long the subjects took to develop angina and changes in their electrocardiogram [ECG] considered indicative of myocardial ischemia.[8]

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[6] Letter from Courtney Riordan, EPA Acting Assistant Administrator for Research and Development, to Charles Powers, Executive Director, HEI, 22 July 1983. Docket No. OAQPS-79-7-IV EPA Central Docket Section, Washington DC. The letter lists several issues raised at the HEI meeting with researchers that Mr. Riordan described as "most pertinent to our request," including "selection of a group of researchers to perform the study which have not been immersed in the CO controversy." EPA did not ask HEI to undertake a quality assurance program for COHb—perhaps because it already had the results of an "interlaboratory comparison of carboxyhemoglobin analysis methods" that its Environmental Criteria and Assessment Office had contracted from a team of CO researchers, including Aronow before his FDA fraud was discovered (Case, McCray, Aronow, Coburn, Chance and Yonetani, contract #D2196NASX), but HEI incorporated such a program in its CO study anyway to compare COHb measurement in split and standard samples by different methods.

[7] The three COOC members already affiliated with HEI were the late Dr. John Tukey, then the Donner Professor of Science at Princeton University who chaired the committee, Dr. Joseph Brain, then and now the Cecil K. and Philip Drinker Professor of Environmental Physiology at Harvard University, and Dr. Roger McClellan, then the President of the Chemical Industry Institute of Toxicology. The three outside experts were the late Dr. Steven Horvath at UC Santa Barbara, the late Dr Stephen Ayres at St. Louis University, and Dr. Stephen Achuff, then and now at Johns Hopkins School of Medicine.

[8] ECG was monitored for "ischemic ST" [IST] segment depressions greater than 0.1mm. The authors reported onset times for each subject but only the mean maximum amplitude, duration, and summed ST score

Unlike Aronow, however, HEI's researchers added a fourth day to the protocol for qualifying lads and introduced additional variation by exposing subjects on three of these four days to individual levels of CO for different lengths of time (either 50, 55, 60, 65 or 70 minutes). Exposures ranged from 42 to 208ppm on the low CO day and 143 to 357ppm on the high CO day. This was contrary to a recommendation from EPA's Clean Air Advisory Committee in December 1980—before HEI's protocol was finalized—that CO studies of angina patients should use exposures of "say 15, 35 and 50ppm."[9]

All the exposures on the low CO day exceeded EPA's one-hour CO NAAQS of 35ppm, and all those on the high day exceeded the agency's one-hour "significant harm level" of 125ppm—a level first designated in 1971 as "immediately dangerous" even to healthy people.[10] The doses were so high that they prompted concerns from EPA staff, who had unsuccessfully urged HEI to study CO exposures at or below the current CO NAAQS limits (US GAO 1986).

The authors reported in their abstracts that all the exposures were double-blind, but they acknowledge in their methods that neither subjects nor researchers were blinded on the 'qualifying' day, when all subjects were exposed first to air and then to 150ppm CO for one hour. The increase in each subject's venous COHb in response to this CO exposure was used to calculate their individual rates of 'CO uptake.' On the three randomized and double-blind study days that followed, subjects were again exposed at rest to either pure air or air mixed with an individually calculated level of CO.

The authors' objective was not to measure the effects of particular levels of CO exposure but the effects associated with particular levels of vCOHb. They specified vCOHb targets of 2.2 and 4.4% in blood samples drawn immediately after 50 to 70 minutes of CO exposure, and levels of 2.0 and 4.0%, in samples drawn immediately after the subjects stopped exercising in fresh air, which rapidly (although only temporarily) lowers vCOHb. Two percent vCOHb was requested by EPA because this was the lowest level at which Dr. Aronow had reported finding a significantly shorter time to the onset of angina (Aronow 1981).

While Dr. Aronow exposed his subjects to only 50ppm for one hour and always directed them to stop exercising at the onset of angina, the HEI team exposed their subjects to considerably greater risk by directing them to continue exercising *with angina* for as long as they could thereafter until they were either too exhausted or in too much pain to continue.[11]

Although each subject was reportedly exposed to a constant level of CO for one hour, the levels inside the chambers fluctuated as the door or some other port was opened to collect blood samples for COHb measurement after exactly 30 and 40 minutes of exposure. The authors acknowledge that the CO exposure levels they report for each subject are actually the average of four 15-minute 'time weighted averages' but they do not report theses values (Allred 1989a, p14, 73).

Given all these sources of variability, it is not surprising that the authors overshot their post-exposure venous COHb targets by approximately 20%. What seems too good to be true is that they nevertheless perfectly met their subsequent post-exercise target on the low CO exposure day—with a mean vCOHb of exactly 2.00%—and almost met the 4% target on the high CO day (mean 3.87%). They do not report the ranges or standard deviations for any of their summary statistics.[12] These can be determined, however, from the individual observations they published in appendices of their HEI report (Allred 1989a, Appendix B, Table B1). The range around the lower mean COHb of 2.0% is

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[9] EPA/SAB/CASAC. Research Needs Assessment for Setting National Ambient Air Quality Standards. Dec. 1983, p32. http://nepis.epa.gov/exe/zyplstmp.cgi/41A221F985C1CBAA85257329006C0876/$File/AMBIENT+AIR+QUALITY+CASAC-83-019_63019_5-25-1995_411.pdf accessed 10/15/2013

[10] US EPA 1971 in 36FR2002. Re-affirmed by US EPA 1980 in 45FR55078.

[11] The average duration of exercise after the onset of angina was about three minutes, individual data were not published.

[12] Means of 2.06% and 4.00 % are reported in Appendix M1 of Allred 1989a. The authors do not explain or acknowledge the discrepancy. Dr. Aronow, in contrast, reported a mean of 2.02% vCOHb with a much tighter range of just 1.8 to 2.3% among 15 subjects exposed to 50ppm for one hour (1981). The authors of the HEI study do not mention Aronow's more precise results or discuss why they did not attempt to replicate his published method.

also implausible: It is perfectly symmetrical and extends from exactly 1.0 to 3.0%. More plausibly, the range around the high mean is less perfect, extending from 2.3 to 5.1%.

The authors report these mean vCOHb levels are associated with modest but statistically significant mean decreases (of between 4 and 12%) in their two primary outcomes: the percent change in the time it took the men to develop angina [ANG] and a specific type of ST segment change in their ECG associated with ischemia [IST].

While these results are still cited by EPA as the best documented effects of low-level CO exposure, the study actually fell far short of its recruiting goals which significantly reduced its statistical power. The authors report their intention was to study 75 subjects and claim they recruited 76, they started with a goal of 150 and stopped after enrolling 107.[13] They also tested but did not report the results of an unspecified number of healthy controls, estimated by this reviewer at 29 to 43.[14] They published complete results for 69 cases, 6 of which they disqualified, leaving 63 in their final analysis. This is just 42% of their goal, and less than the number of contributors acknowledged by HEI's 'Multicenter CO Study Team' [McCOST].

In addition to the study's 10 co-authors, the McCOST included the 6-member 'Advisory' COOC mentioned above, an 11-member Technical Review Panel, a 5-member Quality Assurance Team from the Arthur D. Little [ADL] consulting firm, and HEI's executive director, to whom the ADL auditors sent all their "confidential inspection reports." The investigators worked from 7 sites in 4 states, including the medical schools of 3 universities (at Johns Hopkins, St. Louis and Stanford), and the Harvard School of Public Health. The authors also acknowledged another 47 collaborators by name—including 7 more cardiologists, 6 "data coordinators," and 3 "data checkers"—for a total acknowledged team of 80.

But HEI's McCOST did not have a single principal investigator with overall authority—hence HEI's alphabetical listing of the authors—and it did not follow HEI's original study plan (Cox 1984, Williams 1995). The McCOST took five years and approximately $2.5 million (Jasanoff 1998) to finish a study that EPA originally requested be done in one year for under $300,000.[15]

The authors submitted their final audited report to HEI in November 1987. It was first reviewed by the technical review panel and then accepted by HEI's Health Review Committee in March 1988. The HRC sent it "to the Board of Directors with a strong endorsement and a recommendation to publish the report as soon as possible"(Allred 1989a).

Although the board accepted the report without revision, HEI's first printing of it in 1988 was not publicly released. It was not dated or numbered and distributed only to HEI's advisors and financial sponsors.[16] Despite EPA's urgent need for the study, HEI embargoed the results for more than another year, finally releasing them in November 1989 with a newly printed, dated and numbered cover (HEI version= Allred 1989a, Research Report 25). Its 98 pages include a one-page

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[13] Dr. Roger McClellan, personal communication, 2014

[14] The authors disclose that they tested an unspecified number of healthy controls only in Appendix H, I, M and N of their HEI report (Allred 1989a). The number can be estimated, however, by dividing the 261 blood samples from controls that they acknowledge analyzing for COHb by gas chromatography [GC] in Appendix H by the number of such samples analyzed per person. This was two per day over the three randomized testing days until the authors amended their protocol on August 28, 1985, after which it was three per day, yielding a total of either six or nine samples per person analyzed by GC. The number of samples tested before or after the amendment are not specified, however, so the number of controls who completed the protocol can only be estimated as somewhere between 261 divided by 9 (=29) or 6 (=43.5). If some of the controls did not complete the entire protocol, the total number of controls involved would be larger than these estimates.

[15] Dr. Aronow's angina study for EPA, in contrast, was budgeted at $80,000—half of which was to be paid by EPA—but ended up costing only $16,689, all of it paid by the VA (US GAO 1984). Dr. Aronow completed the study in 48 calendar days, from November 23, 1979 (the Friday after Thanksgiving), to January 11, 1980, and he gave a first draft to EPA's Office of Research and Development just 18 days later. Subtracting weekends and federal holidays, this left just 33 weekdays for him to recruit and test 15 subjects for three days each for a total of 45 visits, or an average of three every two days. Dr. Aronow accomplished this without any reported dropouts and almost entirely by himself. He acknowledges unspecified technical assistance from three individuals and secretarial assistance from a fourth but not this timeline or his VA funding.

[16] Dr. Rashid Shaikh, personal communication, 2012

preface by HEI's Board of Directors praising the study, a two-page table of contents, one page of abbreviations, the authors' 79-page report with 18 appendices, a page "About the Authors," one page of errata, and a 17-page commentary by HEI's Health Review Committee.

HEI embargoed its version until after a 7-page version was accepted and published by The *New England Journal of Medicine* on November 23, 1989 (NEJM version= Allred 1989b), which reportedly took more than one year to get through peer-review (Graham 1991). This was followed 14 months later by the publication of a 44-page version with three appendices in *Environmental Health Perspectives* (EHP version= Allred 1991). The authors also answered letters about the study and two later wrote an editorial about it but in neither context do they acknowledge any doubts about the validity of their methods or results.[17]

A side-by-side reading of their three reports, however, reveals inconsistently reported methods and results. For example, the wide and overlapping ranges of CO to which subjects were exposed on the low and high exposure days are described in the NEJM abstract only as "air containing one of two concentrations of carbon monoxide (117 +/- 4.4 ppm or 253 +/- 6.1 ppm)," without noting that these values are actually means +/- their standard error rather than the more typically presented (and larger) standard deviation.[18] The EHP abstract, in contrast, specifies only exposure to "low and high CO," while the HEI abstract specifies exposure to "air that contained carbon monoxide concentrations calculated to produce approximately 2.2% or 4.4% carboxyhemoglobin...at the end of the exposure period."

The wide and overlapping ranges of vCOHb that resulted from these exposures—from 1.0 to 3.0% on the 2% target day and 2.3 to 5.7% on the 4% target day—are not reported in any of the abstracts or anywhere at all in the NEJM and EHP versions. Only the HEI abstract even acknowledges that "The actual one-minute postexercise levels reached" of "2.0% ± 0.1%" and "3.9% ± 0.1%" are "(mean ± standard error of the mean)." The EHP abstract gives the same values without this critically important parenthetical explanation, while the NEJM abstract does not even include the SEM term. It says only that "exposure to *the lower level* resulted in *a carboxyhemoglobin level* of 2.0 percent" and similarly, that "*the higher level* resulted in *a carboxyhemoglobin level* of 3.9 percent", which misleadingly suggests that all the subjects attainted these specific levels of COHb even though few did [*emphasis added*].

The authors also never explained in any version why they treated these vCOHb results as discrete independent variables when they clearly are continuous and dependent on each subject's unique level and duration of CO exposure. These are the independent variables they should have studied but they do not present any analysis of these dose data. They are shown only in two small scatterplots in appendix C of the HEI version. Even though these figures show that increasing the CO level from 42 to 357 ppm had no consistent effect on either primary outcome, the authors do not mention these negative results in either the NEJM or EHP versions.

I tried contacting the HEI study's corresponding author, Dr. Jane Warren, about my concerns but she would not return my calls. Co-authors and reviewers who agreed to speak with me all strongly defended the study and denied being aware of any misconduct. I asked HEI for access to the study's archive to reanalyze their raw data.[19] HEI's executive director responded four months

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[17] NEJM published two letters from readers about the study and one from all the authors in reply, listing Dr. TE Dahms of St Louis University as the first author and Dr. J Warren of HEI as second (NEJM 1990; 322:1086-1087). HEI does not publish letters and EHP did not publish any about this study. The editorial was written by Drs. SM Weiden and SO Gottlieb: Urban angina, urban arrhythmias: carbon monoxide and the heart. Ann Intern Med. 1990 Sep 1;113(5):337-8.

[18] Of the 63 subjects for whom exposure levels are reported, only one was exposed to exactly 117ppm and only one to exactly 253ppm, and only eight more were exposed to levels within the specified standard errors of these means: six on the low CO day from 113 to 121ppm and two on the high day from 247 to 259ppm. The full range was actually 42 to 357ppm

[19] It is "the policy of the Health Effects Institute to provide access expeditiously to data for studies that it has funded and to provide that data in a manner that facilitates review and validation of the work ." http://www.healtheffects.org/RFA/RFA-AppendixD.htm. Accessed 12/15/13 But HEI's "Special Quality Assurance Procedures" no longer require investigators to preserve an archive of all their study records, as they did before I made this request www.healtheffects.org/RFA/RFA-AppendixC.htm.

later by claiming that he had authorized the disposal of the archive four years earlier, at the request of (and upon the retirement of) Dr. Jane Warren, HEI's Director of Science, who had been the study's coordinator and a co-author.[20]

My ability to re-analyze the study's data is limited, therefore—as is yours—to what the authors published. But a lot can be learned about the study's history, design, and conduct from other sources. Among those I consulted were public comments submitted by HEI to EPA on the CO NAAQS (Cox 1984); HEI's 1985 annual report, which includes a 16-page article about the McCO study, then in its second year (Williams 1985); reports from investigations of both EPA's CO standard and HEI by the US Government Accounting Office (US GAO 1984, US GAO 1986, respectively), a report on HEI's performance by the National Research Council (1993), and other reviews of HEI's work on the study (Jasanoff 1988, Graham 1991). I also interviewed many of the surviving authors and others who either reviewed or oversaw the CO study.[21]

From these sources, I have compiled evidence of many deviations from the norms of publicly-funded biomedical research (Appendix A) and a wide variety of scientific and ethical misconduct (B), including misleading figures, some clearly manipulated, that obscure the study's actual methods and results (C), and misleading tables, many with arithmetic errors and some with fabricated results (D). These appendices are attached for your review, along with highlighted versions of the study showing what text was copied from the HEI version into the NEJM (E) and EHP(F) versions, and what text was changed or deleted (G).

Most damaging to the scientific record—and meeting all published definitions of scientific misconduct—is that the authors appear to have fabricated and/or falsified much of what they reported in their methods, data and conclusions.[22] Less damaging to the factual record but nevertheless of ethical concern are the authors' unnecessary overexposure of both cases and controls, plagiarism of themselves and others, redundant publication of results, guest and ghost misattribution of authorship, and failure to disclose any of the conflicts of interest or bias among themselves and the HEI staff, directors, advisors, and financial sponsors who also contributed to the study in various ways.

It is not clear from my investigation which authors and institutions were aware of the scientific misconduct associated with this study. Even if only a few were directly responsible and their actions uncoordinated or inadvertent, the net effect is the same. The scientific community can no longer have any confidence in the study's results or conclusions regarding the effects of CO exposure on men with coronary artery disease, and regulatory agencies can no longer have confidence in CO standards based on them.

Since the Committee on Publication Ethics [COPE] recommends retracting any published paper whose "findings and conclusions cannot be relied upon," there is no need for the journals involved to determine which of this study's many misrepresentations are due to honest error, innocent oversight or simple sloppiness rather than deliberate misconduct; which authors are

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[20] Dr. Greenbaum, personal communication, 2012.

[21] Personal communications in 2011-2014 with study's co-authors (all except Dr. Walden, who died in 1996, and Drs. Bleecker, Chairman and Warren, who would not take or return calls); McCOST collaborators (Drs. David Stevenson and Henk Vremen); McCOST technical advisors (Drs. Ronald Coburn and Stephen Feinberg), HEI executive directors (Charles Powers 1980-1984, Dr. Rashid Shaikh (co-acting with Dr. Jane Warren) 1987-1988 and 1993-1994, Dr. Andrew Sivak 1989-1992, Dr. Daniel Greenbaum 1994-); HEI's past president, Dr. Donald Kennedy; HEI advisors (Drs. Joseph Brain, Roger McClellan, Bernard Goldstein, James Grizzle, P. Barry Ryan); EPA CASAC advisors (Drs. Milan Hazucha and Stephen Thorn as well as all the HEI advisors except Dr. Grizzle); past and present EPA staff (Lester Grant, Dave Hawkins, Tom McCurdy, David McKee, Ken Sexton); and past EPA-funded CO researchers (Drs. Wilbur Aronow, David Sheps)

[22] The applicable standards are those of COPE (Retractions. Guidance from COPE, accessed 10/28/2013); ICMJE (Recommendations for the Conduct, Reporting, Editing, and Publication of Scholarly Work in Medical Journals: Publishing and Editorial Issues Related to Publication in Medical Journals: Scientific Misconduct, Expressions of Concern, and Retraction. Accessed 10/8/2013); and US EPA (Policy and procedures for addressing research misconduct, accessed 9/25/13). HEI does not have policies posted for investigators or the public regarding standards of scientific integrity for HEI staff or investigators, procedures for investigating alleged misconduct, or procedures for correcting or retracting reports.

responsible for what errors; or which of their other papers may be similarly unreliable.[23] What matters most to the integrity of the published record is simply whether the authors' conclusions are supported by accurately reported methods and results. In the case of HEI's MCCO study, the evidence in the attached appendices shows they are not. To cite some compelling examples:

1) Only two of the 63 cases responded to CO exposures consistent with the authors' hypotheses and the "mean" primary results—namely with greater decreases in their times to the ANG and IST outcomes after exposure to CO compared to after only air, and in a dose response fashion.[24] Another 17 subjects fulfilled the primary hypotheses but with unpredicted and inconsistent patterns of dose-response. *This leaves more than two-thirds who demonstrated better cardiovascular performance after CO exposure compared to before.* These results directly contradict the authors' now widely cited but unjustified conclusion that men with coronary artery disease and stable angina react adversely to brief CO exposures in this range.[25] The results are, however, consistent with many studies published since 1999 showing that some levels of CO are cardio-protective.[26] Had the authors accurately reported their results, they might now be credited with having made this remarkable discovery ten years earlier.

2) The study's three testing sites could not consistently replicate their own or each other's primary results, casting doubt on the validity of their combined means;

3) Quality assurance testing described in the study's Manual of Standard Operating Procedures' to check the accuracy of their vCOHb measurement methods (CO oximetry and gas chromatography) against the Van Slyke method that the authors considered the gold standard were abandoned without any reporting of their results. The study's primary reference laboratory at St. Louis University stopped using its CO-oximeter and did not replace it due to "unresolveable technical difficulties." And even though the president of HEI at the time, Dr. Donald Kennedy, was also president of Stanford University, HEI dismissed a second reference laboratory at Stanford from the study when Dr. Hank Vreman, after months of trying, could not confirm the vCOHb results of the primary laboratory. The HEI version nevertheless includes some of Dr. Vreman's results without his knowledge or consent and without acknowledging his contributions by name;

4) Almost every figure is misleading and some clearly manipulated, with missing and/or extra data points (Appendix C);

5) Almost every table is misleading due to various errors such as mislabeled columns, overstated sample sizes that are not corrected for "trimming," and miscalculated differences between means (Appendix D);

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[23] According to COPE, ORI and others, responsibility for investigating these related issues rests with the authors' employers and funders and should not delay notices of concern or retraction from journal editors if warranted based on the evidence. Only if misconduct is confirmed, of course, would journal editors need to be concerned with the authors' other publications, which according to a search of PubMed may total as many as 1,540. This does not include over 100 other HEI-funded "Research Reports" that Dr. Warren did not co-author but contracted, oversaw and approved as HEI's Director of Research from 1987-1999 and then as its Director of Science from 1999 until her retirement in 2008 (HEI Update, Spring 2008).

[24] When reanalyzed by the percent change in time to each outcome during the exercise sessions conducted pre- and post-exposure on the CO days compared to the air day, the only two subjects who meet the primary hypotheses with consistent dose-response are ID# 104 and 318. When reanalyzed by the absolute change in time, there again just two subjects, but they are not the same: ID# 213 and 334.

[25] The three published versions of Allred *et al* have together been cited over 380 times in other peer-reviewed literature, which is far more than any other CO inhalation study. According to www.GoogleScholar.com as of 10/1/2013, there were 21 citations of the HEI version, 70 of the EHP and 282 of the NEJM. Many of the HEI citations are by EPA staff, who usually cite all three versions together, while Health Canada and WHO Regional Office for Europe cite only the NEJM version in their CO standards. Searching more broadly for any mention of the study on the internet using www.Google.com finds over 23,000 hits for "Allred et al" + "carbon monoxide"

[26] A collection of 27 peer-reviewed studies on PubMed that document cardio-protective properties of CO is available at http://www.ncbi.nlm.nih.gov/sites/myncbi/collections/public/1VgotprOdscOwRSH_g_OKMW

6) Of the 38 cases who were given ID numbers but dropped out before completing all four days of testing [=107-69], only seven are acknowledged and explained. The authors do not give any results for the unspecified number of healthy controls who completed the same protocol or for those who participated in their 1984 pilot study;

7) The authors do not report any signs or symptoms that may have occurred during any of the CO exposures, when CO levels ranged from 42 to 357ppm and each subject's body burden of CO was increasing. If no changes were noted in any subjects during their 50 to 70 minute exposures, this is very significant and should have been reported as it suggests CO exposures at rest in this range do not cause any increased risk of angina or ECG abnormalities. Instead, the authors only report negative outcomes that occurred during the graded exercise testing in fresh air which followed each exposure.

8) The authors acknowledge mean declines of up to 17% in venous COHb during the subjects' brief exercise sessions after inhaling CO, none of which lasted more than 18 minutes. These are surprisingly short half-lives, equivalent to breathing hyperbaric oxygen at rest. The authors do not disclose that they knew this decrease was only a temporary consequence of the increases in respiratory rate and depth that accompany exercise. As one of the COOC advisors published in 1988, vCOHb rebounds *within five minutes* after stopping exercise to almost 100% of its prior level—even with no additional CO exposure—as respiration slows to normal.[27] In contrast, the McCO study specified that blood samples for COHb analysis be drawn *within one minute* of stopping exercise. This significantly underestimated the subjects' COHb levels at the time they developed ANG and IST, which occurred, on average, several minutes before they stopped exercising;

9) Contrary to the authors' conclusions but consistent with other studies, the two primary outcomes of ANG and IST were not consistently correlated with each other.[28] Subjects either experienced angina several minutes before they developed an "ischemic" ST segment change or vice versa, proving that neither is the cause of the other;

10) Also not correlated were the subjects' individual levels of CO exposure and their resulting levels of venous COHb. The authors misrepresented the latter as an independent measure of "CO uptake" and "dose" both during and after exposure even though they knew vCOHb declined faster during exercise as subjects increased their minute ventilation and with it, their rate of CO excretion. The change in each subject's vCOHb after exercise following exposure to fresh air on the control day was more variable, as shown on the y-axis of the scatterplot below. There is no plausible explanation for either the large number of subjects who unexpectedly experienced no change at all in their vCOHb while exercising after exposure to air (along the line y=0) or the complete absence of subjects how experienced changes between zero and -10 or +12%.

The authors do not address these most unlikely findings. They also do not acknowledge or explain why they reported only vCOHb results when their original MSOP specified measuring COHb in arterial blood, which is a more meaningful indicator of absorbed CO dose. While venous blood is less painful to sample, vCOHb is a dependent measure of CO excretion that depends greatly on aCOHb. Arterial and venous COHb both rise during exposure, of course, but arterial does so much faster at first. If exposure continues long enough, arterial and venous CO levels will reach equilibrium with each other and with the inhaled level, but given the range of exposures used in this study, this would have taken at least 5 to 10 hours of continuous exposure. Since the study used exposures of only 50 to 70 minutes, each subject's arterial COHb level would still have been significantly higher than their venous and should have been reported as the authors originally intended.

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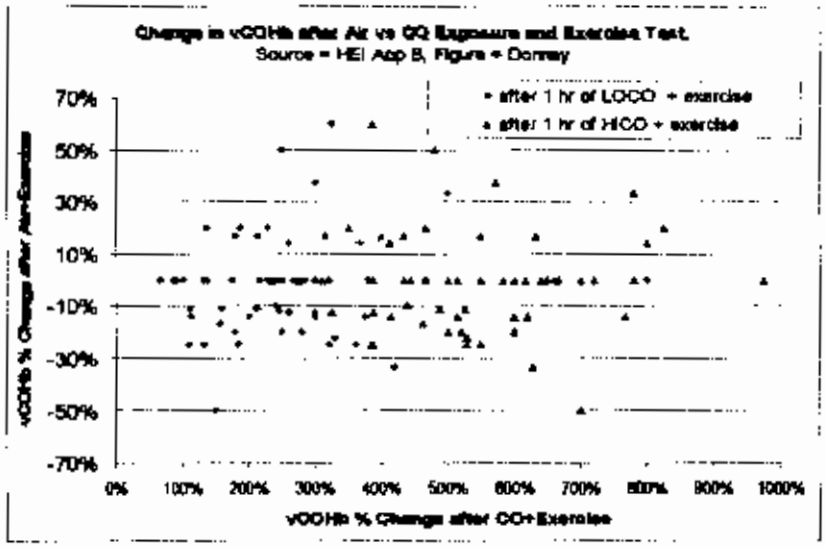
[27] Dr. Steven Horvath et al started this study in 1984 and published it in 1988, a year before the McCO study. Maximal aerobic capacity at several ambient concentrations of carbon monoxide at several altitudes. (HEI Research Report 21)

[28] A collection of 11 peer-reviewed studies on PubMed dating from 1980 that document inconsistent correlations between the time to angina and the time to ST segment change is available at http://www.ncbi.nlm.nih.gov/sites/myncbi/collections/pubs/1HUOmRosy/9Sa3AQjF9OHK/



Given that the McCO study was first published 25 years ago, some may propose letting it rest in peace. But this is not just another old study whose findings are widely recognized as outdated and no longer relevant. In addition to being the "primary basis" for EPA's current CO NAAQS, the study's results are still widely taught in toxicology and continue to garner new citations in the peer-reviewed literature at a rate of more than one per month. It is for these reasons that study's many errors, discrepancies and misrepresentations must either be corrected—which seems impossible now that HEI has discarded the study's archive—or all three versions retracted.

If the authors are not willing to do this, I ask you—the editors of NEJM and EHP and HEI's Board of Directors—to independently retract their papers and publish your reasons for doing so.[29] Either way, the articles and their retraction notices should be permanently linked in all forms of publication (abstracts, full text, and PDFs) as ICMJE and COPE retraction guidelines recommend.[30]

You are welcome to publish any part of this letter or the attached appendices that you think should be preserved in the record of your journal or might be of interest to your readers, perhaps as part of an exchange of correspondence with HEI and the McCO authors. But please note that I am not requesting this and so have made no effort to format this submission according to your instructions for authors.

If you obtain any independent peer-review of my findings, please share the reviewers' comments with me and allow me time to reply. As ORI and EPA guidelines recommend—and as NEJM has done in other cases—I also ask that you acknowledge my contribution in whatever editorial statements you publish about these papers for your readers.[31] Thank you for your consideration.

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[29] The National Library Medicine stipulates that publications may be retracted at the request of any one of the authors, the editor, or the sponsoring institution, which in this case is HEI, although EPA commissioned it.

[30] COPE publishes separate codes of conduct for editors and publishers at http://publicationethics.org/resources/guidelines

[31] Relman AS. Responsibilities of authorship: where does the buck stop? NEJM 1984; 310(16):1048-1049. Office of Research Integrity guidelines are online at http://ori.dhhs.gov/guidelines-whistleblowers and those of EPA at http://ori.hhs.gov/sites/default/files/epapolicy.pdf

Sincerely,

Attachments (electronic versions only: click here to download via Dropbox)

Appendices compiled by Albert Donnay in support of request for retraction

A. Deviations from accepted norms of scientific research in Allred *et al.*
B. Deviations that meet definitions of scientific misconduct in Allred *et al.*
C. Misleading figures in Allred *et al.*
D. Misleading tables in Allred *et al.*
E. Sections of NEJM version copied from HEI version without attribution
F. Sections of EHP version copied from HEI version without attribution
G. Sections of HEI version deleted or changed in the EHP version

cc: Surviving authors of HEI's Multicenter Carbon Monoxide Study Team (all except Dr. Walden)
Surviving members of HEI's CO Oversight Committee (Drs. Achuff, Brain and McClellan)
Surviving members of HEI's Technical Review Panel (Drs. Borer, Coburn, Cohen, DeMets, Fienberg, Furberg and Pitt)
Surviving members of HEI's Health Review Committee (Drs. Upton, Goldstein, Higgins and Grizzle)
Surviving members of EPA's most recent CASAC on CO (in addition to Drs. Brain and Dahms above, Drs. Armistead, Blanc, Cowling, Crapo, Crawford-Brown, Dickerson, Fechter, Frey, Hazucha, Henderson, Kaufman, Kenski, Kleinman, Laden, Penn, Ritz, Roberts, Sweeney and Thom)
Academic Integrity Officers and Institutional Review Boards at Harvard School of Public Health, Johns Hopkins School of Medicine, St. Louis Univ. School of Medicine, and Rancho Los Amigos
EPA Administrator Gina McCarthy
EPA Inspector General Arthur Elkins, Jr.
EPA Scientific Integrity Officer Dr. Francesca Grifo
EPA HEI Advisory Committee, c/o Dan Costa

Certifications

To the Health Effects Institute:

Per HEI's "Policy on the provision of access to data underlying HEI-funded studies," I am hereby informing HEI and the authors of the MCCO study of the findings of my re-analysis, providing you with a complete copy of all that I have submitted to other journals, and giving you an opportunity to respond prior to their publication. As requested, I note explicitly that the views

expressed in this reanalysis are solely my own and not those of the "McCO study authors, HEI or HEI's sponsors," namely the EPA and manufacturers of vehicles and vehicle engines sold in USA.

To the New England Journal of Medicine:

Per NEJM's instructions for authors, I hereby certify that I do not have any financial or other conflicts of interest related to the McCO study, either currently or in the past, although I have previously commented on this study—prior to my discovery of the misconduct I now allege—in public petitions, written comments, and public testimony that I submitted to EPA in 2011 regarding the CO NAAQS then under review, as well as in a statement submitted to the US Court of Appeals for the District of Columbia Circuit in 2012 by the plaintiffs in Communities for a Better Environment et al. v. US EPA, No. 11-1423.

I also filed a provisional patent (July 2013) for a non-invasive method of measuring the relative concentrations of CO and other circulating gases in lungs, arteries, veins, and the average of all tissues, but this has no bearing on the McCO study or EPA's CO NAAQS.

To Environmental Health Perspectives:

Per EHP's instructions, I hereby certify that nothing in this manuscript is redundant or duplicative of anything that I or, to the best of my knowledge, anyone else has previously published on HEI's McCO study. I also certify that "all actual or potential competing financial interests have been declared and that my freedom to design, conduct, interpret, and publish research is not compromised by any controlling sponsor as a condition of review and/or publication."

Acknowledgements

I thank all those involved in the McCO study who have talked with me and answered correspondence about this matter (listed in footnote 4 above), and the librarians at EPA, HEI, and Harvard Law School who provided access to archived documents. I also am very grateful to colleagues at various universities who took the time to advise me on questions of research ethics, statistics, and toxicology, all of whom I choose not to name out of respect for their privacy.

For her assistance in reviewing and editing my research and for her unwavering support of this project, I am most grateful to my wife, Dr. Paige Gossage. Any errors she or my advisors may have missed are my sole responsibility. If readers find any mistakes in the content, please notify me so that I may promptly issue a correction, as recommended by the "*Veritas Vos Liberabit* Code of Ethics in Scientific Work." This code was first posted for students and faculty in the Johns Hopkins Department of Geology in 1965-66 and first published by the *Canadian Mineralogist* (Donnay 1995) but it applies equally to all scientific fields.

References

Underlined titles indicate hyperlinks to the abstract or full text online; book titles are in bold.

Allred EN [1989a], Bleecker ER, Chaitman BR, Dahms TE, Gottlieb SO, Hackney JD, Hayes D, Pagano M, Selvester RH, Walden SM, Warren J. Acute effects of carbon monoxide exposure on individuals with coronary artery disease. Res Rep Health Eff Inst. 1989 Nov;(25):1-79.

Allred EN [1989b], Bleecker ER, Chaitman BR, Dahms TE, Gottlieb SO, Hackney JD, Pagano M, Selvester RH, Walden SM, Warren J. Short-term effects of carbon monoxide exposure on the exercise performance of subjects with coronary artery disease. N Engl J Med. 1989 Nov 23;321(21):1426-32.

Allred EN [1991], Bleecker ER, Chaitman BR, Dahms TE, Gottlieb SO, Hackney JD, Pagano M, Selvester RH, Walden SM, Warren J. Effects of carbon monoxide on myocardial ischemia. Environ Health Perspect. 1991 Feb;91:89-132.

Anderson EW, Andelman RJ, Strauch JM, Fortuin NJ, Knelson JH. Effect of low-level carbon monoxide exposure on onset and duration of angina pectoris. A study in ten patients with ischemic heart disease. Ann Intern Med. 1973 Jul;79(1):46-50.

Aronow WS. 1981. Aggravation of angina pectoris by two percent carboxyhemoglobin. Am Heart J 101:154-157.

Beard RR, Wertheim GA. Behavioral impairment associated with small doses of carbon monoxide. Am J Public Health Nations Health. 1967 Nov;57(11):2012-22.

Committee on Publication Ethics. 2009. Retractions: Guidance from the Committee on Publication Ethics. Published only online, accessed 9/28/13 at: http://publicationethics.org/files/u661/Retractions_COPE_gline_final_3_Sept_09__2_.pdf

Cox A. Chairman, HEI. Letter of September 19, 1984, to EPA in response to request for public comments on "Revisions to the National Ambient Air Quality Standards for Carbon Monoxide, 49 FR 155 at 31923-31926, August 9, 1984." Docket No. OAQPS-79-7-(V-L-2, Central Docket Section, Washington, DC.

Donnay JDH. *Veritas Vos Liberabit*: Code of Ethics in Scientific Work. Canadian Mineralogist, 1995;33(2): inside back cover. Published posthumously by the editor in honor of JDHD; reprinted in CMCC Newsletter (September 2009, p.48), IUCr Newsletter (2009(17)4) and Glass Physics and Chemistry (2010(36)4, p.518).

Graham JD, Holtgrave DR. Predicting EPA's forthcoming CO standards in light of new clinical evidence. Risk Anal. 1991;11(2):325-33.

Graham JD, Holtgrave DR. Carbon Monoxide. In: Graham JD ed., Harnessing Science for Environmental Regulation. 1991, 197-261. New York NY: Praeger

Health Effects Institute Health Review Committee. Health Review Committee's Report. Res Rep Health Eff Inst. 1989 Nov;(25):81-99.

Horvath SM, Ayres SM, Sheps DS, Ware J. Letter of May 25, 1983 to Dr. Lester Grant, including peer review committee reports on Dr. Aronow's studies. EPA Docket No. OAQPS-79-7-(V-H-58. U.S. Environmental Protection Agency, Central Docket Section, Washington, DC. *[note the Central Docket Section cannot find any copies but this report is reviewed in detail in US GAO 1984, p10-11]*

International Committee of Medical Journal Editors. Uniform requirements for manuscripts submitted to biomedical journals: writing and editing for biomedical publication. Accessed at www.icmje.org/index.html#top on 10/1/2013

Jasanoff S. 1988. The Fifth Branch: Science Advisers as Policymakers. Cambridge MA: Harvard Univ Press.

Mintz M. FDA, Citing Phony Evidence, Bars Drug Tests by Researcher. Washington Post, Mar 23, 1983; A23

National Research Council, Commission on Life Sciences, Board on Environmental Studies and Toxicology, Committee to Review the Structure and Performance of the Health Effects Institute. The structure and performance of the Health Effects Institute. Washington DC: National Academy Press. 1985.

Otto DA, Benignus VA, Prah JD. Carbon monoxide and human time discrimination: failure to replicate Beard Wertheim experiments. Aviat Space Environ Med. 1979 Jan;50(1):40-3.

Peterson C. EPA Reviews Carbon Monoxide Data. Washington Post, May 5, 1983[a]; A25

Peterson C. EPA Probe Criticizes a Study Used in Air-Quality Standard. Washington Post, Jun 7, 1983[b]; A17

US Government Accounting Office. 1984. Natural Resources and Environment: Status of EPA's Air Quality Standards for Carbon Monoxide. Washington DC: US GAO. RCED-84-201, Sep 27, 1984

US Government Accounting Office. 1986. Air Quality Standards: The role of the Health Effects Institute in conducting research. Washington DC: US GAO. RCED-86-177BR. Jun 16, 1986

Williams E. An HEI case study: the Multi-center Carbon Monoxide Study. In: Profile 1985: The Health Effects Institute Annual Report. Cambridge MA: Health Effects Institute, 1985, 8-24 *[note this is available only upon request from HEI]*

Abbreviations in Appendices and Affiliations of HEI Contractors

ADL - Arthur D Little Inc. [now defunct], contracted to do quality assurance audits for McCO study
ANG - angina, one of two outcomes designated by authors as 'primary' along with IST
BP - blood pressure
BWP - box and whisker plot
CAD - coronary artery disease
CARB - California Air Resources Board
CI - confidence interval
CO - carbon monoxide
COHb - carboxyhemoglobin [venous unless arterial is specified]
COIOC - CO Oversight Committee, later changed to "Advisory Panel", appointed by HEI
COox - CO oximetry using IL282 from Instrumentation Laboratories unless another device is specified
DP - "double-product" [sic] of heart rate times blood pressure
ECG - electrocardiogram [aka EKG]
EHP - *Environmental Health Perspectives*, published by Natl. Inst. of Environmental Health Sciences
EPA - Environmental Protection Agency. EPA was led by Ruckelshaus under Reagan when the McCO study was commissioned.
GC - gas chromatography, the gold standard for measurement of CO and COHb in blood
HEI - Health Effects Institute, supported during the McCO study with $3 million per year from EPA assistance agreement X-812059 and a matching $3 million from automobile and engine manufacturers (pro-rated to their annual sales in USA)
HR - heart rate
HRC - Health Review Committee appointed by HEI, chaired by Dr. Levy during McCO study
HSPH - Harvard School of Public Health, contracted via Dr. Pagano to manage SADMC
IRB - Institutional Review Board (study approved at least by IRBs at JHU, STL and RLA)
IST - "ischemic" ST segment depression >1mm on ECG, including types 1, 2 and 3 without distinction
JHU - Johns Hopkins University Medical School, then at Key [now called Bayview] Medical Center, contracted to test subjects via Drs. Bleecker and Gottlieb [husband of Dr. Walden, a co-author]
McCO study - HEI's Multi-center Carbon Monoxide Study, contracted by HEI to at least six institutions
McCOST - HEI's Multi-center CO Study Team [initially 11 co-authors, then 10 in NEJM and EHP versions]
MSOP - Manual of Standard Operating Procedures finished by McCOST in March 1985
NAAQS - National Ambient Air Quality Standards [CO= 9ppm max avg/8hours & 35ppm max avg/1hour]
NEJM - *The New England Journal of Medicine*, published by the Massachusetts Medical Society
O2Hb - oxyhemoglobin [venous unless arterial is specified]
PI - principal investigator
QuAP - Quality Assurance Program, contracted via Dr. Dahms at STL to run primary COHb reference lab
QuAT - Quality Assurance Team directed by Dr. Sivak at ADL who then became executive director of HEI
RLA - Ranchos Los Amigos Medical Center, contracted to test subjects via Drs. Hackney and Selvester
SADMC - Statistical and Data Management Center at HSPH contracted to support McCO study
SCP= - scatterplot
SD - standard deviation
SEM - standard error of the mean =SD/(square root (n-1))
SSS - summed ST score
STAN - Stanford University, contracted via Dr. Stevenson to support McCO study as COHb reference lab
STL - St. Louis University Medical School, contracted to test subjects via Dr. Chaitman
TRP - Technical Review Panel, appointed by HEI to advise McCOST, chaired by same Dr. Levy as HRC

# # #

U.S. Environmental Protection Agency
Office of Inspector General

2005-4-00054
March 31, 2005

At a Glance

Reported Outlays Under EPA Grant R828112-01 Health Effects Institute

What We Found

We questioned $2,009,473 of reported outlays because the Health Effects Institute did not maintain the necessary documentation to fully support the reported costs, as required by Federal regulations. Employee time sheets did not specifically identify the EPA grant as a chargeable activity and were not used as the basis for charging labor and related costs to the grant. The recipient charged time for specific employees even though the employees might have worked on other non-grant activities. In addition, the recipient charged travel and other costs to the grant without determining the allocable benefit of such costs.

The Health Effects Institute did not agree with our conclusions. The Institute stated that it had only one final cost objective and all of its cost were allocable to the EPA grant. This position is inconsistent with the Institute's accounting records which identified two cost objectives, one for the EPA grant and one for industry. Besides the automotive industry, the Institute received funds from several other sources.

What We Recommend

We recommend that EPA (1) obtain sufficient documentation to support the outlays of $2,009,473 in accordance with EPA regulations or disallow the costs from Federal grant participation, (2) place the recipient on a cost reimbursement payment basis and review the supporting documentation for all claims prior to payment until such time as the recipient can demonstrate that it has addressed its financial management weaknesses, and (3) ensure the recipient's indirect cost rate proposal includes information for identifying direct and indirect costs, and an explanation of how these costs are accounted for in the accounting system.

[redacted]

From: [redacted]
Sent: Friday, June 06, 2014 3:19 PM
To: [redacted]
Subject: Hotline 2014-152

This is acknowledgement that your request for retraction has been forwarded to the EPA Science Integrity Official as Hotline 2014-152. [redacted]

Special Agent [redacted]
Desk Officer for the OIG Hotline
US EPA, OIG, Office of Investigations HQ
1200 Pennsylvania Ave NW Mailcode 2431T
Washington, DC 20460

Hotline - 202-566-2476 or 888-546-8740
Hotline Fax 202-566-0814 Web Address oig_hotline@epa.gov

HOTLINE 2015-086

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF
INSPECTOR GENERAL

January 7, 2015

MEMORANDUM

SUBJECT: Office of Inspector General Hotline Complaint 2015-086

FROM: [redacted]
Headquarters, Office of Inspector General

TO: Francesca T. Grifo, Ph.D.
Scientific Integrity Official

The Environmental Protection Agency (EPA), Office of Inspector General (OIG), Hotline has completed the review of allegations from [redacted] contacted the Hotline to request a review of allegations of science misconduct in a Carbon Monoxide Exposure Study.

Our review is completed and we have determined that the allegations raised do not rise to the level of criminal charges. Moreover, the allegations seem to fall under administrative procedures. The OIG does not plan on any further investigation, audit, or evaluation for his allegations. The OIG review package and results are attached for your information.

We established EPA OIG Hotline Number 2015-086, to document the complaint; however, the information provided does not fall within the scope of complaints the OIG investigates. However, we are referring this matter to your office for whatever action you determine necessary. Please inform the Hotline a[redacted] within the next 5 calendar days that this referral was received. Please do not hesitate calling Special Agent [redacted] at [redacted] if there are any questions.

Attachment:

cc: Carolyn Copper, AIG OPE OIG

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
OFFICE OF INSPECTOR GENERAL

1200 SIXTH AVENUE, SUITE 1920
SEATTLE, WA 98101

CASE #: n/a **CROSS REFERENCE #:**

TITLE: [redacted] Complaint – Scientific Misconduct in Carbon Monoxide Exposure Study

PREPARED BY: [redacted]

MEMORANDUM OF ACTIVITY

NARRATIVE:

[redacted] Electronic Crimes Division, Office of Investigations, Office of Inspector General reviewed several documents submitted as an OIG Hotline complaint from [redacted] regarding allegations of scientific misconduct (conflict of interest, plagiarism, modifying data in publications related to the same study, etc.) in studies on the exposure of people to carbon monoxide (scientific shorthand – CO) in ai[redacted] llegations were previously referred to [redacted] EPA Science Advisory Board alleging a conflict of interest of three Science Advisory Board members, as OIG Hotline Complaint #2013-159 on May 16, 2013, (Attachment 1) and to Dr. Francesca T. Grifo, Science Integrity Officer, EPA, requesting retraction of an EPA-funded study which [redacted] believes contains errors, as OIG Hotline Complaint #2014-152 on June 6, 2014. (Attachment 2)

The following documents fro[redacted] are attached to the OIG Hotline Complaint referrals #2013-159 and #2014-152:

+ Attachments to Complaint #2013-159
  - email from [redacted] o [redacted] EPA, dated May 15, 2013
  - email from [redacted] o [redacted] EPA, dated May 12, 2013

+Attachments to Complaint #2014-152
  - email from [redacted] to [redacted] EPA, dated May 29, 2014
  - email from [redacted] to Gina McCarthy, Arthur Elkins, et al., EPA, dated May 19, 2014
  - An open letter requesting retraction of all three published versions of the "Multicenter Carbon Monoxide Study" by the Health Effects Institute's Multicenter CO Study Team, from [redacted] to Editor in Chief, New England Journal of Medicine; Editor in Chief, Environmental Health Perspectives; and the Health Effects Institute Board of Directors, dated May 19, 2014.

Attachments to OIG Hotline Complaint # 2013-159

Email from [redacted] to [redacted], EPA, dated May 15, 2013

This email reiterates some of the issues raised by [redacted] in his email a year earlier to [redacted] EPA, alleging conflicts of interest for individuals appointed to the EPA's Clean Air Science Advisory Board (a Federal Advisory Committee Act group). The following are highlights of some of the issues raised in the [redacted] email:

- Alleges undisclosed conflicts of interest of 3 EPA appointees to the Clean Air
- Science Advisory Committee (CASAC) working on the [redacted]
- Provides an update that [redacted]
- Requests that [redacted] be barred from serving again on advisory committees, if [redacted] allegation of undisclosed conflicts of interest are substantiated.
- [redacted] opines that [redacted] failed to investigate [redacted] allegations of conflicts of interest, once saw the names of the appointees. [redacted] requests that [redacted] who replaced [redacted] investigate these allegations.
- [redacted] states in his email, that [redacted] officer told him, she would investigate [redacted] allegations when she was instructed to investigate.
- [redacted] states in his email that the relevant information for his allegations is contained in Section 6 on page 10 of the disclosure statements, EPA Form 3110-48(8-11), and in the CASAC committee meeting transcripts when *studies conducted by these appointees were discussed.*

Email from [redacted] to [redacted] EPA, dated May 12, 2013

According to this email, the email was a follow-up to a telephone conversation between [redacted] and [redacted] on February 16, 2012, when [redacted] made allegations of conflicts of interest against certain members of the CASAC. The following are highlights from this email:

- Alleges that CASAC members failed to disclose their roles in key studies to other members of the panel if and when their studies were discussed.
- Alleges that CASAC members failed to recuse themselves from discussing or voting on their own studies (or charge questions related to their studies).
- Questions whether the CASAC members failed to disclose their roles in key studies on their 3100-48 disclosure forms that EPA considered before nominating the appointees to the CASAC.
- Allegations are made against three individuals

[redacted]

- Alleges that the Allred study was co-funded through HEI, by EPA.

Attachments to OIG Hotline Complaint #2014-152

Email from [redacted] to [redacted] EPA, dated May 29, 2014

This is a follow-up to a telephone call between [redacted] and [redacted] Hotline Coordinator, EPA OIG, on May 29, 2014. The following are highlights from this email:

- [redacted] is requesting retraction of a $2.5 million study commissioned by EPA with the Health Effects Institute (HEI).
- [redacted] is concerned about a study on carbon monoxide (CO) which was published twice in 1989, by the New England Journal of Medicine and the Health Effects Institute. This study is still cited as the "primary basis" for the carbon monoxide National Ambient Air Quality Standard, on the assumption that the methods and results are valid.
- The carbon monoxide study has been endorsed by the past three review panels appointed by EPA, even though all three review committees were chaired by HEI-affiliated scientists. The latest review, in [redacted]
- [redacted] makes an allegation that [redacted] and the Science Advisory Board (SAB) did not disclose this source of potential bias to the other review committee members or the public.
- [redacted] would like the OIG to consider whether HEI should be sanctioned in some manner, if [redacted] allegations of scientific misconduct are correct.
- [redacted] would like the OIG to instruct the HEI, to stop throwing away the archives of the EPA-funded research without first offering the documents to EPA to archive.
- [redacted] has made his allegations of scientific misconduct known to the HEI Board of Directors and the journals who published the study results. To date, they have not responded to [redacted]

Email from [redacted] to Gina McCarthy, Arthur Elkins, et al., EPA, dated May 19, 2014

This email references [redacted] "open letter" requesting retraction of the three published studies (see below), and was addressed to Gina McCarthy, Administrator, EPA; Arthur Elkins, Inspector General, EPA; Dr. Francesca Grifo, Science Integrity Officer, EPA; and Dr. Dan Costa, National Program Director for Air, Climate, Energy Research Program, EPA.

An open letter requesting retraction of all three published versions of the "Multicenter Carbon Monoxide Study" by the Health Effects Institute's Multicenter CO Study Team, from [redacted] to Editor in Chief, New England Journal of Medicine; Editor in Chief, Environmental Health Perspectives; and the Health Effects Institute Board of Directors, dated May 19, 2014.

<u>An open letter requesting retraction of all three published versions of the "Multicenter Carbon Monoxide Study" by the Health Effects Institute's Multicenter CO Study Team (Allred et al.), by [redacted] dated May 19, 2014</u>

This letter by [redacted] was addressed to the editors of the New England Journal of Medicine, Environmental Health Perspectives, and to the Board of Directors of the Health Effects Institute requesting retraction of published articles related to the Multicenter Carbon Monoxide Study. The articles [redacted] has requested retractions for were published in 1989 (2 papers) and 1991 (one paper). In this letter he alleges several reasons for retracting the published papers. Among these are:

- For background, these papers were used to establish the National Ambient Air Quality Standards for carbon monoxide in the U.S.A.; National Ambient Air Quality Objectives for carbon monoxide in Canada; Air Quality Guidelines for Europe by the World Health Organization Regional Office for Europe; and other countries.
- [redacted] alleges that the Multicenter Carbon Monoxide Study, aka., the Allred, et al., study, is fundamentally flawed and the study's conclusions are not supported by its results, "*...some of which appear to be too good to be true.*"
- EPA commissioned the Allred, et al., study, in 1983, after a similar flawed study conducted by a Dr. Aronow at the Veterans Administration.
- According to [redacted] Dr. Aronow never received approval from the Veterans Administration for conducting his research for the EPA.
- Dr. Aronow admitted to the U.S. Food and Drug Administration that he fabricated test data for cardiac drugs.
- EPA continued to promote Dr. Aronow's carbon monoxide study as the best available evidence to support the National Ambient Air Quality Standard for carbon monoxide.
- In March 1983, the Washington Post published an article regarding Dr. Aronow's misconduct.
- EPA then appointed a "special peer review committee" to review Dr. Aronow's work. The peer review committee could not review the original documentation because it had been discarded by Dr. Aronow. According to [redacted] without the original documentation, the committee decided they could not rely on Dr. Aronow's work and recommended EPA conduct additional research to resolve this impasse.

- Because of this impasse and recommendations from the peer review committee, EPA commissioned the Health Effects Institute to replicate Dr. Aronow's 1981 study on carbon monoxide.
- [redacted] allegations are difficult to follow regarding a workshop, in July 1983, which was convened by the Health Effects Institute and attended by EPA, the Aronow review committee and other researchers to discuss possible carbon monoxide study designs.
- According to [redacted] this workshop came one month after the Health Effects Institute's Health Research Committee had issued a request for investigator-initiated studies on cardiac effects of carbon monoxide exposure.
- The Health Effects Institute appointed three of its Health Research Committee members and three outside experts (two of these experts were part of the peer review of Dr. Aronow's study), to a Carbon Monoxide Oversight Committee (COOC) tasked with organizing the study. The COOC's name was then changed to the HEI Advisory Committee in August 1983, and tasked to select investigators, plan the study, and to provide guidance throughout the study.
- According to [redacted] the COOC planned the study first and then hired cardiologists to conduct the study.
- The study assessed the effect of carbon monoxide exposures in men with coronary disease, and used an endpoint of how long an exposure to carbon monoxide was needed for the study participant to develop angina or a change in their electrocardiograms. This was similar to the study conducted by Dr. Aronow.
- According to [redacted] the Allred, et al., study added a fourth day to their study which was not part of the Aronow study, and also included different exposure times to carbon monoxide which was not part of the Aronow study. The carbon monoxide concentrations which subjects of the Allred, et al., study were exposed to exceeded the EPA's air quality standard of 35 ppm for a one-hour exposure and on the high carbon monoxide exposure day exceeded the EPA's one-hour "significant harm" exposure limit of 125 ppm.
- [redacted] alleges that the Allred, et al., study's objective was not to measure the effects of exposure to carbon monoxide but to measure the effects of venous carbon monoxide-hemoglobin. (Chemist's Note – It is well established that carbon-monoxide will associate with hemoglobin in blood *more readily than oxygen. Hemoglobin associates with oxygen to carry* oxygen around the circulatory system where it is needed by cells of the body.)
- Again comparing the Aronow study to the Allred, et al., study, [redacted] alleges that Aronow only exposed subjects to 50 ppm carbon monoxide and instructed them to stop exercising when they experienced the onset of angina versus the Allred study, where subjects were directed to continue exercising after the onset of angina until the subjects were exhausted or were in too much pain to continue.
- [redacted] contends that the Allred, et al., study overshot its post-exposure venous carbon monoxide-hemoglobin target by 20% [redacted] cites in a previous paragraph with reported values of 2.2% and 4.4%. But then alleges the Allred, et al., study almost perfectly met their post-exercise target exposures were 2% and 4% for venous carbon monoxide-hemoglobin.

- [redacted] states that the Allred, et al., study had a goal of studying 150 subjects but only published work on 63 cases, after they disqualified results on 6 subjects (total of 69 subjects), or as [redacted] stated in his letter they only tested 42% of their goal. (Chemist's Note – Not enough information is provided to determine if the reduced number of study cases was due to budget or other constraints.)
- [redacted] in his letter, tries to make a point that the 63 cases in the Allred, et al., study is less than the number of contributors listed in the HEI's Multicenter Carbon Monoxide Study Team. (Chemist's Note- Not sure why this point is being made? More researchers (total of 80) than study participants (63 cases).)
- [redacted] in his letter, criticizes the Allred, et al., study because it did not have a single principal investigator who had overall authority for the study. Reporting Chemist is not aware of this being a requirement for all studies. He is also critical that the Multicenter Carbon Monoxide Study took five years to complete (in 1989) and cost over $2.5 million instead an EPA request to complete the study in one year at a cost of under $300,000.
- [redacted] alleges that the HEI embargoed their copies of the Allred, et al., study until after a shorter 7-page version of the study results was published in The New England Journal of Medicine, which took a year to get through the peer-review process, and then a later 14-page publication in Environmental Health Perspectives. (Chemist's Note – [redacted] six months to a year for peer-reviewed publications is not unusual.)
- [redacted] in his letter, then gets into a comparison of the three publications for the Allred, et al., study, i.e., the New England Journal of Medicine publication (7 pages), the Environmental Health Perspectives publication (44 pages), and the HEI report (98 pages), and alleges inconsistently reported methods and results.
- According to [redacted] he tried to contact the HEI's corresponding author, Dr. Jane Warren, who refused to return his calls, and other study co-authors and reviewers defended the study and were not aware of any misconduct.
- [redacted] requested access to the HEI study's archive to reanalyze their data. HEI's director responded to [redacted] four months later saying that the archive had been disposed of four years earlier, at the request of Dr. Jane Warren, which was also about the time she retired. Reporting Chemist is not aware of any records retention schedule that applies to private entities.
- [redacted] states in his letter that because of the disposal of the study archive his, and therefore the Agency's ability, to review the data is limited to what was published by the authors.
- [redacted] states that he has compiled evidence of many deviations covering many different areas. These deviations are attached as appendices to his complaint:
    - Appendix A – Deviations from the norm of biomedical research
    - Appendix B – A variety of scientific and ethical misconduct
    - Appendix C – Misleading, and some clearly manipulated, figures which obscure the actual methods and results

- Appendix D – Misleading tables, many with arithmetic errors, and some with fabricated results.
  Reporting Chemist has not reviewed these appendices, and there are also appendices E thru G, attached to this complaint.

[redacted] hen reiterates his allegation of scientific misconduct and alleges the authors fabricated or falsified much of what they reported in their methods, data, and results. He again raises the ethical concern of overexposing the human subjects of the study, redundant publication, guest and ghost attribution of authorship, etc.

- [redacted] hen reiterates that the scientific community can no longer have confidence in this study's results and regulatory agencies can no longer have confidence in the carbon monoxide standards based upon the study.
- [redacted] refers to the Committee on Publication Ethics recommendation to retract any published paper whose "findings and conclusions cannot be relied upon." [redacted] s conclusion is that based upon his evidence in the appendices attached to this complaint, the study conclusions cannot be relied upon because they are not supported by accurately reported methods and results. [redacted] hen lists 10 "compelling examples" in his complaint.

Summary

In an attempt to categorize the numerous allegations raised by [redacted] in his two complaints, the allegations seem to fall into the following areas:

- Conflict of interest by appointees to the [redacted]
- Similarities in the Aronow and Allred studies. The initial carbon monoxide study which was published in approximately 1981, by Dr. Aronow, was for various reasons discarded, and replaced with data from the Allred, et al., study which was published in approximately 1989 [redacted] raises similar allegations for discarding the Allred study which were raised about the Aronow study.
- [redacted] makes several allegations of scientific misconduct regarding the Allred study.

Allegation of Conflict of Interest

In OIG Complaint #2013-159, [redacted] alleges a conflict of interest for three appointees to [redacted]

[redacted]

Reporting Chemist has not reviewed any applicable conflict of interest policies which may be applicable to EPA appointees to scientific work groups/Federal Advisory Committees, but when the agency wants national experts to work on a scientific work group, the potential applicant pool may be rather limited because of the expertise desired.

Does a conflict of interest determination need to be made for these allegations?

Similarities in the Initial Aronow Study and the Allred Study

According to allegations in [redacted] complaint, the initial study on carbon monoxide published by Dr. Aronow in approximately 1981, was set aside or discarded when allegations were raised that Dr. Aronow conducted the study without the approval of the Department of Veterans Administration, alludes to not having approval to conduct research with human subjects of cardiac drugs for pharmaceutical companies, and fabrication of drug data to the Food and Drug Administration. When EPA appointed a special peer review committee to review the Aronow carbon monoxide study, most of the data (documentation) had been discarded, and therefore EPA commissioned additional research on carbon monoxide exposure.

In [redacted] complaint regarding the Allred study, he raises allegations that the human subjects were exposed to high concentrations of carbon monoxide which exceeded EPA significant harm level of 125 ppm, set in 1971. The Allred study did not exactly match the Aronow study, the Allred study added an extra day of carbon monoxide exposure. Now, approximately thirty years after the Allred study was published, the original documentation has been discarded, after the retirement of one of the study authors. Reporting Chemist is not aware of a records retention schedule which would apply to research conducted by a private entity with government funds.

[redacted] allegations regarding the Allred study, seem to be similar to the allegations leading to the discarding of the Aronow study on carbon monoxide: questions the ethics of the study on human subjects based upon carbon monoxide exposure concentrations; alleges fabrication of data in the published study results; and now questions the study thirty years after it was completed and the original documentation has been discarded and is no longer available for review.

Allegations of Scientific Misconduct

[redacted] sent his "open letter" with his allegations of scientific misconduct to the New England Journal of Medicine, the journal Environmental Health Perspectives, and to the Health Effects Institute. Reporting Chemist would recommend reviewing how the New England Journal of Medicine and Environmental Health Perspectives editors respond to [redacted] allegations of scientific misconduct. These journals have a process on how to handle such allegations. If the journal editors decide that the articles published as part of the Allred study

need to be retracted, then the agency should review any reasons for such a retraction and determine if the Allred study needs to be retracted.

[redacted] in his complaint, has stated that the backup documentation for the Allred study has been discarded, after one of the authors retired, and it has been almost 30 years since the study was published. So it would be difficult to perform an in-depth technical review or assessment of the original data, in light of the allegations raised by [redacted]

At this time, Reporting Chemist does not believe that the allegations raised by [redacted] would rise to the level for criminal charges, these allegations seem to fall under administrative procedures regarding scientific misconduct allegations.

Attachments

1. OIG Hotline Complaint #2013-159 referral to [redacted] EPA Science Advisory Board, dated May 16, 2013.

2013-159
referral.pdf

2. OIG Hotline Complaint #2014-152 referral to Dr. Francesca T. Grifo, EPA Science Integrity Officer, dated June 6, 2014.

2014-152
refferal.pdf

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

OFFICE OF
THE INSPECTOR GENERAL

January 15, 2015

[redacted]

Dear [redacted]

Thank you for your recent inquiry. The U.S. Environmental Protection Agency (EPA), Office of Inspector General (OIG), Fraud, Waste, and Abuse Hotline receives complaints of fraud, waste, and abuse within EPA programs and operations, including mismanagement or violations of law, rules, or regulations by EPA employees or program participants.

We established EPA OIG Hotline Number 2015-086, to document a final review of your allegations regarding the Science Misconduct in Carbon Monoxide Exposure Studies. The review of your complaint included two previous Hotline Numbers 2013-159 and 2014-152.

Our review is completed and we have determined that the allegations you raised do not rise to the level of criminal charges. Moreover, the allegations seem to fall under administrative procedures. We are forwarding the result of our review to the EPA Science Integrity Officer. This Hotline is closed with no further OIG investigation, audit, or evaluation.

Should you uncover instances of fraud, waste, and abuse within EPA programs or operations, please contacts the OIG Hotline. We appreciate your support in protecting human health and the environment. Address for Hotline is 1200 Pennsylvania Ave, 2431T, Washington, DC, 20460. Please contact at this address or call me at [redacted] if there are any questions.

Sincerely,

[redacted]

Special Agent, Hotline Manager
OIG, Office of Investigations

[redacted]

From: [redacted]
Sent: Thursday, January 15, 2015 4:09 PM
To: [redacted]
Subject: EPA OIG Hotline 2015-086
Attachments: 2015-086 closeout letter.pdf

Please find attached a letter for this Hotline Closing. As the letter states it has been sent back to Ms. Grifo. [redacted]

Special Agent [redacted]
Desk Officer for the OIG Hotline
US EPA, OIG, Office of Investigations HQ
1200 Pennsylvania Ave NW Mailcode 2431T
Washington, DC 20460
[redacted]

Hotline - 202-566-2476 or 888-546-8740
Hotline Fax 202-566-2599 Web Address oig_hotline@epa.gov

[redacted]

From: [redacted]
Sent: Thursday, January 15, 2015 2:26 PM
To: [redacted] Grifo, Francesca
Subject: RE: Hotline 2015-086 [redacted]
Attachments: 2015-086 Closeout Letter fig mjo.doc

Hi, [redacted]

Francesca and I have reviewed the draft response to [redacted] Please see the attached file with our comments. We would prefer that you delete the sentence regarding forwarding the result of your review.

Please let me know if you have any questions.

Thank you for the opportunity to review the draft.

Regards,

[redacted]
Office of the Science Advisor
[redacted]

From [redacted]
Sent: Tuesday, January 13, 2015 2:37 PM
To: [redacted]
Subject: RE: Hotline 2015-086 [redacted]

Let me know if the OIG Letter is ok. I would like to send it out this week

Special Agent [redacted]
Desk Officer for the OIG Hotline
US EPA, OIG, Office of Investigations HQ
1200 Pennsylvania Ave NW Mailcode 2431T
[redacted]

Hotline - 202-566-2476 or 888-546-8740
Hotline Fax 202-566-2599 Web Address oig_hotline@epa.gov

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From: [redacted]
Sent: Wednesday, January 07, 2015 4:36 PM
To: [redacted]

Cc: Grifo, Francesca
Subject: FW: Hotline 2015-086 [redacted]

Forgot to include you on the email. Sorry

Special Agent [redacted]
Desk Officer for the OIG Hotline
US EPA, OIG, Office of Investigations HQ
1200 Pennsylvania Ave NW Mailcode 2431T
Washington, DC 20460
[redacted]

Hotline - 202-566-2476 or 888-546-8740
Hotline Fax 202-566-2599 Web Address oig_hotline@epa.gov

From: [redacted]
Sent: Wednesday, January 07, 2015 4:26 PM
To: Grifo, Francesca
Subject: Hotline 2015-086 [redacted]

Please find attached the referral memo to you for the [redacted] allegations. I have also attached the proposed letter to [redacted] from the OIG. Please review the letter and let me know if there are any changes and if I can send it out. I will be doing the same for [redacted] Happy New Year [redacted]

Special Agent [redacted]
Desk Officer for the OIG Hotline
US EPA, OIG, Office of Investigations HQ
1200 Pennsylvania Ave NW Mailcode 2431T
Washington, DC 20460
[redacted]

Hotline - 202-566-2476 or 888-546-8740
Hotline Fax 202-566-2599 Web Address oig_hotline@epa.gov

[redacted]

From: [redacted]
Sent: Friday, December 12, 2014 1:32 PM
To: [redacted]
Cc: Grifo, Francesca
Subject: Re: OIG meeting re. CO study

Thanks for letting me know about the OIG meeting on Dec 19th with Dr. Grifo to review my concerns about the Allred CO study.

I am grateful that a chemist on OIG's staff has done an independent review and hope his findings can be publicly released at some point, regardless of whether any action is taken on them.

[redacted]

[redacted]

From: [redacted]
Sent: Wednesday, December 10, 2014 1:33 PM
To: [redacted]
Subject: RE: OIG meeting re. CO study

I thought we were meeting about your complaint and three others that I have. However, I was wrong and the meeting was for something else.

Special Agent [redacted]
Desk Officer for the OIG Hotline
US EPA, OIG, Office of Investigations HQ
1200 Pennsylvania Ave NW Mailcode 2431T
Washington, DC 20460
[redacted]

Hotline - 202-566-2476 or 888-546-8740
Hotline Fax 202-566-2599 Web Address oig_hotline@epa.gov

[redacted]

Sent: Wednesday, December 10, 2014 1:29 PM
To: [redacted]
Cc: Grifo, Francesca
Subject: Re: OIG meeting re. CO study

Thanks for correcting me-- I must have misunderstood what you told me.

So what did you call to tell me about if not a meeting on Dec 11?

[redacted]

On Wed, Dec 10, 2014 at 1:02 PM, [redacted] wrote:

The meeting on Thursday is not about your complaint. I will get back to you on the OIG response. [redacted]

Special Agent [redacted]
Desk Officer for the OIG Hotline
US EPA, OIG, Office of Investigations HQ
1200 Pennsylvania Ave NW Mailcode 2431T
Washington, DC 20460
[redacted]

Hotline - 202-566-2476 or 888-546-8740

Hotline Fax 202-566-2599 Web Address oig_hotline@epa.gov

[redacted]

Sent: Tuesday, December 09, 2014 2:57 PM
To: [redacted]
Cc: Grifo, Francesca
Subject: OIG meeting re. CO study

[redacted]

Thanks for letting me know that EPA's OIG and Dr. Grifo will be meeting on Dec 11 to discuss my letter of May 19, 2014, regarding the carbon monoxide study that EPA commissioned from the Health Effects Institute in 1983.

Can you please tell me if you were able to send the OIG investigators either of the subsequent emails about this matter that I copied to you on July 29 ["EPA requirements for project managers to report misconduct allegations to OIG"] and Nov 28 ["Addendum to concerns about Allred et al CO study"] ?

I believe these are pertinent not only to the question of whether the Allred study is sufficiently "sound" for EPA to keep citing it as the primary basis for the CO NAAQS, but also to the question of whether the OIG should fine or disbar HEI for its role in this fraudulent study--or perhaps just require it to repay EPA for some or all of the $2.5 million cost?

What concerns me most as both a scientist and a taxpayer are that HEI continues to get about $17 million per year in EPA funding even though its senior staff:

a) submitted final results from the CO study to EPA in 1989 that they knew but did not disclose had been obtained without all the required IRB approvals [missing Harvard's] and which also were in many ways fabricated, falsified, and plagiarized [with results copied without credit from the Harvard doctoral dissertation of Cathie Spino];

b) discarded the CO study's archive in 2008 without informing EPA; and

c) misrepresented the CO study as sound in letters written in 2014 to EPA's Mel Peffers and the editor-in-chief of Environmental Health Perspectives in response to my letter of May 19, but without rebutting any of the over 150 examples of error, misrepresentation, and research misconduct that I documented.

EPA also has not been well served by two of the [redacted] I realize that EPA's OIG has already rejected my concerns about their undisclosed conflicts of interests but I hope you will reconsider this matter in light of the additional evidence of fraud that I've since submitted.

I look forward to learning whether the OIG shares any of my concerns.

Thanks again for keeping me informed.

[redacted]

[redacted]

From: Copper, Carolyn
Sent: Tuesday, December 09, 2014 7:34 PM
To: [redacted]
Subject: RE: Scientific Misconduct complaints

Thanks [redacted] Francesca asked to meet with me on a report recommendation matter – which is totally separate from these misconduct issues OI is working on. I don't plan to get into the scientific misconduct issues in my meeting tomorrow since OPE is not involved and we shouldn't represent those issues for OI. Please follow-up with Francesca directly, or via [redacted] if that's the process Patrick wants you to use.

~Carolyn

From: [redacted]
Sent: Tuesday, December 09, 2014 12:15 PM
To: Copper, Carolyn
Subject: FW: Scientific Misconduct complaints

I talked to Ms. Grifo this morning regarding [redacted] called me yesterday and left a voicemail. [redacted] comments on them is below. She informed me of a planned meeting this Thursday. Do you want me to attend to discuss these two? [redacted]

Special Agent [redacted]
Desk Officer for the OIG Hotline
US EPA, OIG, Office of Investigations HQ
1200 Pennsylvania Ave NW Mailcode 2431T
Washington, DC 20460
[redacted]

Hotline - 202-566-2476 or 888-546-8740
Hotline Fax 202-566-2599 Web Address oig_hotline@epa.gov

From: [redacted]
Sent: Tuesday, December 09, 2014 11:11 AM
To: [redacted]
Subject: FW: Scientific Misconduct complaints

[redacted]

I tried to synopsize things for the [redacted] complaints yesterday, because I did not know when the meeting with Grifo was. Below is what I sent [redacted] yesterday, sorry I did not cc you on this. Please look over the information below, and give me a call if we need to discuss these further or if we need to bounce it around a bit for a better understanding.

FYI, I put together an MOA trying to summarize all of [redacted] complaints and then grouped them into three categories. I put this in the system several weeks ago for approval, and sent [redacted] an email that this was in the system, but he still has not looked at it. I don't want to release draft/unapproved documents to others.

I am working on an MOA to try to discuss some of the issues in th complaint, but with 160 pages of stuff to wade through, it will take a while to summarize it. (b)(5) - deliberative process

See below. I can understand where s coming from because these papers and the results presented have significant policy issue/regulatory implications, and of course they come to different conclusions – impact from lead drinking water lines versus no impact from lead drinking water lines.

Electronic Crimes Division
Office of Inspector General
U.S. Environmental Protection Agency

From
Sent: Monday, December 08, 2014 9:18 AM
To:
Subject: Scientific Misconduct complaints

I don't know when you plan on holding your monthly/quarterly (?) meeting with Francesca Grifo to discuss the various scientific misconduct complaints which we are working on. The following is provided as input for your meeting:

1. I have noticed that some of these complaints are crossing my desk and Francesca's desk also. What is the appropriate protocol for communication between our offices – management level or is it OK if I talk with her? This is just to avoid any duplication of efforts.
2. complaint.
   a. This in the complaint about the carbon monoxide air standard and studies that led to setting the carbon monoxide in air standard.
   b. I have not changed my previous opinion that I do not think this rises to a criminal matter.
   c. When I briefly talked with Francesca for about 5 minutes, when she was out her last month, she said she has had a couple of experts prepare a point by point technical rebuttal t allegations.
   d. also filed a request for retraction of the research articles from the carbon monoxide study which were published in two peer reviewed scientific journals. I don't think either journal issued a retraction.
   e. When I previously looked at this I was only looking at it from a technical point of view. Bu in his allegations has also raised a conflict of interest allegation and I don't know if this has been addressed. The conflict of interest allegation is that some of the personnel involved with preparing the atter involved in EPA workgroup meetings that reviewed the data used to makes the allegation that because these people on here is a conflict of interest. I am not sure if the EPA workgroup members are considered part of a Federal Advisory Committee Act (FACA) group or what conflict of interest guidelines/requirements might apply in this situation.
3. complaint
   a. The complainant, has conducted research on the potential for lead exposure from older lead water pipes. This was a big deal back in the DC area several years ago because lead drinking water lines are still in service there, and in other cities as well. This compliant with attached articles is about 160 pages long.

b. The crux of the argument is whether lead is released due to galvanic corrosion when only part of a lead drinking water line is replaced with copper drinking water line. Galvanic corrosion occurs when two dissimilar metals are joined together, ie., lead pipes and copper pipes, and is lead released due to this galvanic corrosion. The galvanic corrosion would occur where the pipes meet. The most common example of galvanic corrosion is using sacrificial zinc anodes on a steel boat hull, to reduce the rusting of the steel hull.

c. There is a difference in the laboratory experiments conducted by [redacted] He used a static test system where he filled pipe sections with water and let them sit for days to weeks, and then measured the lead that was leached/released from the pipes. The Boyd, et al, study which [redacted] takes issue with used a flow through system, where pipe sections were connected to a reservoir and pump system, and the water was continuously pumped through the pipe sections. Needless to say [redacted] experiments showed that lead was released from the pipes, above drinking water criteria, but the Boyd study showed lead did not exceed drinking water criteria.

d. [redacted] has gone through a couple of rounds of letters to the editor of the Journal of the American Water Works Association (J AWWA) challenging the Boyd study findings. Both the [redacted] and Boyd study results have been cited by Congress, one study says lead pipes are a concern (can lead to lead levels about the drinking water criteria) and possible source of lead in drinking water, and the other study says there is not a concern from lead pipes. The J AWWA editors have published all the papers with links about the controversy involved by these authors and their studies. The bottom line of the editors is that there is controversy and differing results from the scientific process, which needs additional study to determine which results may be correct. The editors point out that both studies were conducted in the laboratory and have not looked at real life situations, where the results could be different than the laboratory experiments. Here is the J AWWA editorial response:

> ***The JEAB responds:*** The board members recognize that scientific knowledge is an ever-evolving endeavor. An important process for adding new knowledge to the scientific literature is manuscript preparation, peer review, manuscript revision, publication, and an open discussion of the results within the scientific community. This is the process being applied to the ongoing scientific debate regarding the topic of lead release following partial lead service line replacements. Board members are confident that the Journal is fulfilling its role by bringing the different perspectives to light. They assessed the comments that had been made through the letters regarding the article in question and found the following:
>
> • The manuscript was fully and fairly assessed by a technical editor and three reviewers with expertise in the subject matter.
>
> • The three reviewers made substantial comments to the authors. In the revised manuscript, the authors addressed these comments to the satisfaction of the reviewers. At no point during the review process did any of the reviewers call Figures 9 and 10 into question. Most of their concerns centered around the exclusion of lead particulates in the analytical methods and on shortcomings of the experimental apparatus to simulate actual field conditions.
>
> • All parties agreed that there is a need for more research to determine how translatable these data are to real water systems.
>
> • The accusation that conclusions were reached by the authors before the experimental data were received was addressed by Boyd et al when they stated that they had been collecting such data for a longer period of time than that confined to the experiments.
>
> • Boyd et al responded to questions regarding Figures 9 and 10 by explaining that a mistake was introduced by their in-house graphic artist. The board has suggested that this error be corrected by way

of the authors submitting an erratum for publication in Journal AWWA.
• The board recommends that readers interested in further information on this debate read the public project paper, Review of Previous Water Research Foundation Projects on Galvanic Corrosion (www.waterrf.org/resources/Lists/PublicProjectPapers/Attachments/3/4349_LiteratureReview.pdf).

e. [redacted] also makes an allegation that parts of the Boyd study journal manuscript (conclusions) were written before the experiments were conducted. This could be of concern, ie., time travel type allegation. But [redacted] did not include any definite examples to support this allegation in his complaint. The J AWWA editors touched on this allegation in their response (4th bullet) above.
f. I am not seeing anything in this allegation that rises to a criminal type issue, in my opinion. I need to write up a summary for the file.

Call me if you wish to discuss any of these issues.

[redacted]
Electronic Crimes Division
Office of Inspector General
U.S. Environmental Protection Agency
[redacted]

[redacted]

From: [redacted]
Sent: Tuesday, October 07, 2014 1:28 PM
To: [redacted]
Subject:

Is your office handling this? You were going to check and get back to me. [redacted]

Special Agent [redacted]
Desk Officer for the OIG Hotline
US EPA, OIG, Office of Investigations HQ
1200 Pennsylvania Ave NW Mailcode 2431T
Washington, DC 20460
[redacted]

Hotline - 202-566-2476 or 888-546-8740
Hotline Fax 202-566-2599 Web Address oig_hotline@epa.gov

[redacted]

From: Copper, Carolyn
Sent: Monday, September 29, 2014 10:56 AM
To: [redacted]
Cc:
Subject: [redacted]

Thanks [redacted] It looks like [redacted] has identified some important issues.

OPE is not doing any additional work on this complaint. The thrust of the complaint is scientific misconduct (Falsification, fabrication, plagiarism). If there is nothing found there, or nothing that can be investigated due to elapsed time, then I think we need to coordinate with the SIO, since this matter was also on her list of complaints.

~Carolyn

From: [redacted]
Sent: Sunday, September 28, 2014 2:53 PM
To: Copper, Carolyn; [redacted]
Subject: FW: [redacted]

[redacted] comments on the complaint. Can you share with the team members doing the work with your team members Maybe we can get together to discuss OIG action if any? [redacted]

Special Agent [redacted]
Desk Officer for the OIG Hotline
US EPA, OIG, Office of Investigations HQ
1200 Pennsylvania Ave NW Mailcode 2431T
Washington, DC 20460
[redacted]

Hotline - 202-566-2476 or 888-546-8740
Hotline Fax 202-566-2599 Web Address oig_hotline@epa.gov

From: [redacted]
Sent: Thursday, September 25, 2014 5:21 PM
To: [redacted]
Cc:
Subject: RE: [redacted]

[redacted]

Now that I had a chance to look at this again. I remember giving it an initial read. [redacted]

(b)(5) - Deliberative Process [redacted]

(b)(5) - deliberative process

[redacted]

[redacted]
Electronic Crimes Division
Office of Inspector General
U.S. Environmental Protection Agency
[redacted]

From: [redacted]
Sent: Thursday, September 25, 2014 8:52 AM
To: [redacted]
Subject: [redacted]

Just checking in to see if you had a chance to look at this allegation? [redacted]

Special Agent [redacted]
Desk Officer for the OIG Hotline
US EPA, OIG, Office of Investigations HQ
1200 Pennsylvania Ave NW Mailcode 2431T
Washington, DC 20460
[redacted]

Hotline - 202-566-2476 or 888-546-8740
Hotline Fax 202-566-2599 Web Address oig_hotline@epa.gov

[redacted]

From: [redacted]
Sent: Tuesday, September 09, 2014 4:06 PM
To: Copper, Carolyn
Subject: RE: Hotline complaint - Response from NEJM

Will do.

Special Agent [redacted]
Desk Officer for the OIG Hotline
US EPA, OIG, Office of Investigations HQ
1200 Pennsylvania Ave NW Mailcode 2431T
Washington, DC 20460
[redacted]

Hotline - 202-566-2476 or 888-546-8740
Hotline Fax 202-566-2599 Web Address oig_hotline@epa.gov

From: Copper, Carolyn
Sent: Tuesday, September 09, 2014 4:04 PM
To: [redacted]
Cc: Grifo, Francesca; [redacted]
Subject: FW: Hotline complaint - Response from NEJM

[redacted] – in [redacted] recent email (see attached), he asked us to send him a copy of any records/decisions we got from the other parties he made complaints to. The attachment 'Response to [redacted] is a June 2014 response to [redacted] from the NEJM. Since we received it, and [redacted] claims he has not, please provide it to him.

Thanks ~ Carolyn

From: [redacted]
Sent: Tuesday, September 09, 2014 2:26 PM
To: Copper, Carolyn
Subject: Hotline complaint - Response from NEJM

Hi Carolyn – Attached is the response letter from New England Journal of Medicine regarding the compliant and request for redaction (very short). Please let me know if you would like to talk with Dr. Drazen and I will work to set something up.

[redacted]

U.S. Environmental Protection Agency
Office of Inspector General

1595 Wynkoop St.
Denver, CO 80202

From: [redacted]
Sent: Monday, September 08, 2014 12:31 PM
To: [redacted]
Subject: Your Inquiry

Dear [redacted]

Pursuant to our telephone conversation of this morning, please find attached Dr. Drazen's response to [redacted] retraction request. If you have questions, he would be happy to discuss them with you by phone. I can set up a time for you.

Kind regards,
[redacted]

[redacted] | *Executive Assistant to the Editor-in-Chief* | **The New England Journal of Medicine** | **NEJM Group**
10 Shattuck Street, Boston, MA 02115 | [redacted] | Fax: 781-207-6529 | [redacted]

Brown, Clay

From: Copper, Carolyn
Sent: Monday, September 08, 2014 3:35 PM
To: [redacted]
Cc:
Subject: Re: Missing attachment [redacted]

Thanks for the quick work [redacted] Please offer my availability to speak with anyone at NEJM about our need to determine how they have responded.

Sent from my iPhone

On Sep 8, 2014, at 12:45 PM, [redacted] wrote:

> Hi Carolyn – I talked to the NEJM Editor-and-Chief Dr. Drazen's assistant. Dr. Drazen is currently [redacted] She stated that NEJM responded to the complainant via letter on June 6, 2014. She is checking with NEJM counsel and Dr. Drazen to see if she can e-mail a copy of the response letter.

[redacted]
U.S. Environmental Protection Agency
Office of Inspector General
1595 Wynkoop St.
Denver, CO 80202

From: Copper, Carolyn
Sent: Monday, September 08, 2014 9:00 AM
To: [redacted]
Cc: [redacted]
Subject: Fwd: Missing attachment. [redacted]

Good Morning [redacted] -- Regarding this complaint, OI is going to delve a little deeper into the misconduct allegations. As I mentioned in an earlier email I think we need to follow up with the NEJM to determine if they are looking into [redacted] complaint and if not why not. Since he has sought a remedy with other parties we need to determine status. [redacted] original complaint has the NEJM addressee he sent his complaint to. mark my calendar for a two week follow up (sept 22) with you, or a team member you assign this to you, to discuss. If you have any questions, let's discuss tomorrow. Thanks ~ Carolyn

Sent from my iPhone

Begin forwarded message:

> **From:** [redacted]
> **Date:** September 8, 2014 at 7:53:34 AM EDT

To: "Copper, Carolyn" <Copper.Carolyn@epa.gov>
Subject: Fwd: Missing attachment. [redacted]

FYI. Attachments requested. [redacted]

Sent from my iPhone

Begin forwarded message:

[redacted]

Date: September 5, 2014 at 3:39:31 PM EDT
To: [redacted]
Subject: Re: Missing attachment

[redacted]

[redacted]

Thanks for following up on my complaint.
Here is a link to a dropbox folder from which all the appendices can either viewed directly or downloaded and then viewed.

[redacted]

If EPA staff are going to review paper copies, please ask them to use a color printer so they can read the tables and figures.

Please note that I have not yet received any reply to the over 150 examples of error and misconduct documented in these appendices -- not from the authors of the study nor from anyone at HEI, NEJM and EHP.

If EPA staff receive any reply to my allegations from any of these parties, I would appreciate their sharing it with me [assuming it is not marked confidential by the sender], or at least letting me know so I can file a FOIA to request it.

Thanks again.

[redacted]

On Wed, Sep 3, 2014 at 9:18 AM [redacted] wrote:

[redacted] could send me the following for further review of your complaint? [redacted]

1) copies of the 'Attachments' referenced on page 15/18 of the letter [redacted] sent the

NEJM? These attachments presumably provide support for the specific allegations of misconduct and are critical for evaluating the complaint.

Here's how the attachments are described in [redacted] letter to NEJM:

"Attachments (electronic versions only: click here to download via Dropbox)

A. Deviations from accepted norms of scientific research in Allred *et at.*

B. Deviations that meet definitions of scientific misconduct in Allred *et at.*

C. Misleading figures in Allred *et at.*

D. Misleading tables in Allred *et at.*

E. Sections of HEJM version copied from HEI version without attribution

F. Sections of EHP version copied from HEI version without attribution

G. Sections of HEI version deleted or changed in the EHP version

Special Agent [redacted]
Desk Officer for the OIG Hotline
US EPA, OIG, Office of Investigations HQ
1200 Pennsylvania Ave NW Mailcode 2431T
Washington, DC 20460
[redacted]

Hotline - 202-566-2476 or 888-546-8740

Hotline Fax 202-566-2599 Web Address oig_hotline@epa.gov

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[redacted]

From: Copper, Carolyn
Sent: Monday, September 08, 2014 10:06 AM
To: [redacted]
Subject: Re: Missing attachment, [redacted]

[redacted] just want to be sure we're on the same page and OI has plans to review the misconduct allegations.
Thanks, Carolyn

Sent from my iPhone

On Sep 8, 2014, at 7:58 AM, [redacted] wrote:

> Thanks [redacted]
>
> Sent from my iPhone
>
> On Sep 8, 2014, at 7:53 AM, [redacted] wrote:
>
> > FYI. Attachments requested. [redacted]
> >
> > Sent from my iPhone
> >
> > Begin forwarded message:
> >
> > [redacted]
> > **Date:** September 5, 2014 at 3:39:31 PM EDT
> > **To:** "Brown, Clay" <Brown.Clay@epa.gov>
> > **Subject: Re: Missing attachment**
> > [redacted]
> >
> > Thanks for following up on my complaint.
> > Here is a link to a dropbox folder from which all the appendices can either viewed directly or downloaded and then viewed.
> >
> > [redacted]
> >
> > If EPA staff are going to review paper copies, please ask them to use a color printer so they can read the tables and figures.
> >
> > Please note that I have not yet received any reply to the over 150 examples of error and misconduct documented in these appendices -- not from the authors of the study nor from anyone at HEI, NEJM and EHP.
> >
> > If EPA staff receive any reply to my allegations from any of these parties, I would appreciate their sharing it with me [assuming it is

not marked confidential by the sender], or at least letting me know so I can file a FOIA to request it.

Thanks again,

[redacted]

On Wed, Sep 3, 2014 at 9:18 AM, [redacted] wrote:

[redacted] could send me the following for further review of your complaint? [redacted]

1) copies of the 'Attachments' referenced on page 15/18 of the letter [redacted] sent the NEJM? These attachments presumably provide support for the specific allegations of misconduct and are critical for evaluating the complaint.

Here's how the attachments are described in [redacted] letter to NEJM:

"Attachments (electronic versions only: click here to download via Dropbox)

A. Deviations from accepted norms of scientific research in Allred *et at.*

B. Deviations that meet definitions of scientific misconduct in Allred *et at.*

C. Misleading figures in Allred *et at.*

D. Misleading tables in Allred *et at.*

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F. Sections of EHP version copied from HEI version without attribution

G. Sections of HEI version deleted or changed in the EHP version

Special Agent [redacted]
Desk Officer for the OIG Hotline
US EPA, OIG, Office of Investigations HQ
1200 Pennsylvania Ave NW Mailcode 2431T
Washington, DC 20460
[redacted]

Hotline - 202-566-2476 or 888-546-8740

Hotline Fax 202-566-2599 Web Address oig_hotline@epa.gov

[redacted]

From: [redacted]
Sent: Wednesday, September 03, 2014 5:27 PM
To: Copper, Carolyn
Cc: Sullivan, Patrick F.; [redacted]
Subject: [redacted]

Yes, as you are aware, [redacted] looks at the allegations when they come in and OI's Chemist looks at the more complicated scientific cases.

From: Copper, Carolyn
Sent: Wednesday, September 03, 2014 3:54 PM
To: [redacted]
Cc: Sullivan, Patrick F.; [redacted]
Subject: [redacted]

Very responsive. Thanks. This would seem to mean it will be important for OI to review the alleged examples of scientific misconduct in [redacted] complaint, before referring to the SIO for action.

From: [redacted]
Sent: Wednesday, September 03, 2014 2:05 PM
To: Copper, Carolyn
Cc: Sullivan, Patrick F.; [redacted]
Subject: R[redacted]

Carolyn:

Reference is made to your request for a response to question #2 listed below concerning scientific misconduct and the statute of limitations. Statutes of limitations are created by legislature and may vary depending on the situation. The rules for criminal actions are different from civil actions and there are situations that stop the clock. Therefore, I believe we will need to examine each case individually. Additionally, since it involves an interpretation of the law, we should get guidance from either the Office of Counsel or the U.S. Attorney's Office before we commit resources to an old out of date case. Please let me know if that was responsive to your question.

Thank You,

[redacted]

From: Copper, Carolyn
Sent: Wednesday, September 03, 2014 9:04 AM

To: [redacted]
Cc: [redacted] Sullivan, Patrick F.; Grifo, Francesca
Subject: [redacted]

Thanks [redacted] Also, an OI answer to the highlighted will greatly facilitate our progress and decisions on this complaint.

From: [redacted]
Sent: Wednesday, September 03, 2014 8:39 AM
To: Copper, Carolyn
Cc: [redacted] Sullivan, Patrick F.; Grifo, Francesca
Subject: Re [redacted]

I will get the attachments. [redacted]
Sent from my iPhone

On Sep 2, 2014, at 12:25 PM, "Copper, Carolyn" <Copper.Carolyn@epa.gov> wrote:

> All – I've reviewed this and need 2 additional things from OI to help with decision-making:
>
> 1) copies of the 'Attachments' referenced on page 15/18 of the letter Mr. [redacted] sent the NEJM? These attachments presumably provide support for the specific allegations of misconduct and are critical for evaluating the complaint.
>
> Here's how the attachments are described in [redacted] letter to NEJM:
>
> "Attachments (electronic versions only: click here to download via Dropbox)
> A. Deviations from accepted norms of scientific research in Allred *et at.*
> B. Deviations that meet definitions of scientific misconduct in Allred *et at.*
> C. Misleading figures in Allred *et at.*
> D. Misleading tables in Allred *et at.*
> E. Sections of HEJM version copied from HEI version without attribution
> F. Sections of EHP version copied from HEI version without attribution
> G. Sections of HEI version deleted or changed in the EHP version
>
> 2) Since the original research and publication was in1989 (25 years ago), even if scientific misconduct was found, is there a statute of limitations in effect? This pertains to criminal matters, not any matters related to whether 'bad science' has been propagated.
>
> 3) Since [redacted] has also raised this matter to HEI and the journals that published the questioned work, and asked for a remedy, I see some value in contacting those organizations to find out the status of their review and decision making. OPE can do this and will make an attempt to do this.

Thanks ~ Carolyn

From: [redacted]
Sent: Tuesday, August 19, 2014 1:09 PM
To: Grifo, Francesca; Copper, Carolyn; [redacted]
Subject: RE: [redacted]

FYI, Attached is the referral to Ms. Grifo from the Hotline. Please let me know when you want to discuss.

Special Agent [redacted]
Desk Officer for the OIG Hotline
US EPA, OIG, Office of Investigations HQ
1200 Pennsylvania Ave NW Mailcode 2431T
Washington, DC 20460
[redacted]

Hotline - 202-566-2476 or 888-546-8740
Hotline Fax 202-566-2599 Web Address oig_hotline@epa.gov

From: Grifo, Francesca
Sent: Tuesday, August 19, 2014 12:06 PM
To: [redacted] Copper, Carolyn; [redacted]
Subject: [redacted]

Hi there –
Doubtless you have seen the correspondence from [redacted] alleging misconduct as regards some HEI studies on carbon monoxide. As I understand it he has written to the OIG and [redacted] asked that we deal with the complaint he submitted to you all.
On a separate track, he has written the Administrator and copied me and [redacted] This is in controlled correspondence and needs to be addressed [redacted] has been tasked with drafting the response to this controlled correspondence and asked if the letter could come from me.

Recently I corresponded with [redacted] to give him an idea of our scheduling for evaluating his claims and he responded with the request that this go back to you. I concur since with his reasoning since the allegation concerns scientific misconduct.

We need to either tell him you will look into it or tell him no one is looking into it and resolve this because I will need to know this in order to respond to his letter to the Administrator.

Thanks for any guidance you can give me. I am anxious to get this settled. I look forward to meeting with you all next month to discuss scientific misconduct and in particular plagiarism and how we intend to ensure that someone at the Agency is in a position to make sure that people are not getting away with unacceptable behavior that falls between the cracks of our current system.

Again – thank you so much!

Francesca

Francesca T. Grifo, Ph. D.
Scientific Integrity Official
US EPA Office of the Science Advisor
202-564-1687
www.epa.gov/research/htm/scientific-integrity.htm

[redacted]

From: [redacted]
Sent: Wednesday, August 20, 2014 10:25 AM
To: [redacted]
Subject: [redacted]
Attachments: 2013-159 referral.pdf; 2014-152 audit.pdf; 2014-152 refferal.pdf

Forgot to add you to the cc line. [redacted]

Special Agent [redacted]
Desk Officer for the OIG Hotline
US EPA, OIG, Office of Investigations HQ
1200 Pennsylvania Ave NW Mailcode 2431T
Washington, DC 20460
[redacted]

Hotline - 202-566-2476 or 888-546-8740
Hotline Fax 202-566-2599 Web Address oig_hotline@epa.gov

From: [redacted]
Sent: Wednesday, August 20, 2014 10:02 AM
To: Copper, Carolyn
Cc: Patrick F. Sullivan (Sullivan.Patrick@epa.gov)
Subject: RE [redacted]

Carolyn, to the best of my knowledge there has been no OI review of this matter. [redacted] informed me in telephone call of an OIG Audit in 2005, which is attached. I asked OA if there was any follow-up from 2005 audit and I was told there was none. He also filed a complaint in 2013, Hotline 2013-159, (attached) which was referred to the Science Advisory Board. I reviewed his complaint from an OI perspective and if there were criminal allegations there may be statute of limitation concerns. However, OI could be included in the OPE and OA review to make sure this is true if his allegations are substantiated. [redacted]

Also, I will be out of the office August 25-29

Special Agent [redacted]
Desk Officer for the OIG Hotline
US EPA, OIG, Office of Investigations HQ
1200 Pennsylvania Ave NW Mailcode 2431T
Washington, DC 20460
[redacted]

Hotline - 202-566-2476 or 888-546-8740
Hotline Fax 202-566-2599 Web Address oig_hotline@epa.gov

From: Copper, Carolyn
Sent: Tuesday, August 19, 2014 5:58 PM
To: [redacted] Grifo, Francesca; [redacted]
Subject: RE: [redacted]

Thanks [redacted]

Thanks [redacted] for your phone call and email. I'm going to be TDY Wed-Fri of this week, so today was a bit backed up trying to prepare for a few days out. I've not had a chance to talk to our Hotline staff or investigators. However, my initial reaction is that under the Scientific Integrity Policy Coordination Procedures, OIG has the lead and is the primary responder on allegations related to scientific misconduct. If OIG has determined that allegations of misconduct aren't merited but there may be other integrity matters that need to be addressed, we can then refer those matters to SIO. Since I don't know what OIG's decision was, if any, on [redacted] scientific misconduct allegations (i.e., "Assuming the EPA's OIG agrees that the evidence I've compiled documents scientific misconduct on the part of HEI in this study [defined as fabrication, falsification and/or plagiarism]" I'd like to find that out first and then propose we talk no later than next Monday. I've already sent a calendar hold for a time that looked available for all.

[redacted] – if OI or others in OIG made an initial determination on [redacted] allegations regarding scientific misconduct, can you send that to me?

I hope this helps move us toward a solution ~ Carolyn

From: [redacted]
Sent: Tuesday, August 19, 2014 1:09 PM
To: Grifo, Francesca; Copper, Carolyn; [redacted]
Subject: RE: [redacted]

FYI, Attached is the referral to Ms. Grifo from the Hotline. Please let me know when you want to discuss.

Special Agent [redacted]
Desk Officer for the OIG Hotline
US EPA, OIG, Office of Investigations HQ
1200 Pennsylvania Ave NW Mailcode 2431T
Washington, DC 20460
[redacted]

Hotline - 202-566-2476 or 888-546-8740
Hotline Fax 202-566-2599 Web Address oig_hotline@epa.gov

From: Grifo, Francesca
Sent: Tuesday, August 19, 2014 12:06 PM
To: [redacted] Copper, Carolyn; [redacted]
Subject: [redacted]

Hi there –

Doubtless you have seen the correspondence from [redacted] alleging misconduct as regards some HEI studies on carbon monoxide. As I understand it he has written to the OIG and [redacted] asked that we deal with the complaint he submitted to you all.
On a separate track, he has written the Administrator and copied me and [redacted] This is in controlled correspondence and needs to be addressed. [redacted] has been tasked with drafting the response to this controlled correspondence and asked if the letter could come from me.

Recently I corresponded with [redacted] to give him an idea of our scheduling for evaluating his claims and he responded with the request that this go back to you. I concur since with his reasoning since the allegation concerns scientific misconduct.

We need to either tell him you will look into it or tell him no one is looking into it and resolve this because I will need to know this in order to respond to his letter to the Administrator.

Thanks for any guidance you can give me. I am anxious to get this settled. I look forward to meeting with you all next month to discuss scientific misconduct and in particular plagiarism and how we intend to ensure that someone at the Agency is in a position to make sure that people are not getting away with unacceptable behavior that falls between the cracks of our current system.

Again – thank you so much!

Francesca

Francesca T. Grifo, Ph. D.
Scientific Integrity Official
US EPA Office of the Science Advisor
202-564-1687
www.epa.gov/research/htm/scientific-integrity.htm

Brown, Clay

From: [redacted]
Sent: Friday, August 01, 2014 1:11 PM
To: [redacted]
Cc:
Subject: Re: EPA requirements for project managers to report misconduct allegations to OIG

[redacted]

I just found a more recent EPA guidance document than the 9/13 version I sent before.

There is a 3/14 version at

http://www.nsf.gov/pubs/policydocs/rtc/agencyspecifics/epa_314.pdf

The article on Research Misconduct appears unchanged except for renumbering -- it is now 11 instead of 17.

[redacted]

On Tue, Jul 29, 2014 at 3:57 PM, [redacted] wrote:

[redacted]

Below is the link to the EPA reporting regs I was telling you about.
They are dated Sept 2013.

I am glad to hear that HEI promptly reported my allegations of misconduct to you as required.

The EPA guidance directing grant project managers to report certain types of scientific misconduct allegations to the OIG is in Article 17 Section 1 on page 11-12.

I believe parts A, B, D, F and G all apply in this case given the broad.scope of issues raised in my letter of May 19 that HEI shared with you in June.

Since it looks like the decision about whether to notify the OIG and when is yours, please let me know if and when you forward my letter and appendices with HEI's reply to your OIG contact.

Please note that from my perspective, HEI's recent responses are just as fraudulent as the original study in terms of misrepresenting the results of their review to you, the editor of NIEHS and perhaps other federal officials as well.

HEI also appears to.have violated EPA guidelines about how to handle such allegations by not giving the authors of the study an opportunity to reply either to my allegations or to HEI's conclusions before the results were communicated to EHP.and EPA.

Even though the statute of limitations has long passed for any civil or criminal penalties related to the conduct and reporting of the original study (circa 1983-1991), I believe HEI's recent denial letters do meet EPA's current defintion of research misconduct.

They convey new misinformation about the study that I allege was fabricated and falsified by HEI staff while their salaries were being paid in part by HEI's current EPA grant.

[redacted]

https://www.google.com/url?q=http://www.nsf.gov/pubs/policydocs/rtc/agencyspecifics/epa_913.pdf&sa=U&ei=667TU-LjH8mKyATy5YKQDA&ved=0CBMQFjAD&usg=AFQjCNGTMqxSphEm2Z5iSC8HpNYDq7fGXw

[redacted]

From: [redacted]
Sent: Friday, August 01, 2014 12:40 PM
To: Grifo, Francesca
Cc: [redacted]
Subject: Re: Retraction request

Dr. Grifo,

Thanks for your prompt reply.

Given that your office is so overworked and understaffed, can you please just return this matter to [redacted] at the OIG Hotline without further delay so he can reopen the case and promptly screen for assignment to some more appropriate office(s) within OIG ?

As outlined in my prior email, 6 of my 7 appendices document examples of federally-prohibitied research misconduct and fraud that are more appropriately OIG's purview than yours.

Also, can you please send me any written comments you may have received from the other EPA staff with whom you shared my letter and appendices? Or tell me their names so I may file a FOIA request for them? I'd like to see what errors, if any, they've identified in my analyses so I may correct them.

Thank you.

[redacted]

On Thu, Jul 31, 2014 at 5:15 PM, Grifo, Francesca <Grifo.Francesca@epa.gov> wrote:

Dear [redacted]

Please be patient. As we have explained to you, we have a large workload and a small staff. I have been at the Agency a short time and we are working hard to create the mechanisms we need to address allegations and fully implement the Scientific Integrity Policy. We get to things as quickly as possible. We will visit this in detail and together with the OIG make a decision as to the best place for its resolution. As soon as we have made that decision, we will let you know.

Sincerely,

Francesca

Francesca T. Grifo, Ph. D.

Scientific Integrity Official

US EPA Office of the Science Advisor

202-564-1687

www.epa.gov/research/htm/scientific-integrity.htm

[redacted]

Sent: Thursday, July 31, 2014 5:09 PM
To: Grifo, Francesca
Cc: [redacted]
Subject: Re: Retraction request

Dr. Grifo

EPA Scientific Integrity Official

Dear Dr. Grifo,

[redacted]at EPA OIG's Hotline tells me he formally assigned my May 19 letter requesting retraction of the HEI Multicenter Study of Carbon Monoxide to your office at your request on June 6, as Hotline case #2014-152.

He told me he did so without first reading my letter and attachments to see if I alleged any misconduct that is by statute the OIG's responsibility to investigate and prosecute (such as violations of EPA research misconduct regulations or federal laws like the Clean Air Act),

or whether I alleged only less serious issues of "scientific integrity" that your [redacted] tells me you are authorized to "evaluate and assess" as EPA's Scientific Integrity Official. For the record, she insisted your office would not be getting involved in doing any investigations, issuing any subpoenas, taking any testimony, or imposing any penalties.

Given this pretty clear division of responsibilities between OIG and OSI , both [redacted] told me they assumed you would promptly return to the OIG for its consideration any evidence of research misconduct for which grantees could be penalized, such as fabrication, falsification and plagiarism.

I certainly expected the same based on what you told me earlier was your merely "moral authority" to advise those involved in cases of misconduct among EPA staff, grantees and contractors.

It has now been over 7 weeks since [redacted] sent you my allegations, and [redacted] tells me she knows of many EPA staff who have reviewed them at your request. I, however, have still not received an acknowledgement from your office that you received them or that you are now conducting some kind of "assessment" in lieu of an actual investigation.

Assuming you have now read the letter and all the appendices I submitted, please tell me how many of the issues I documented you plan to return to the OIG for investigation and how many you are going to continue to evalnate in your office.

Among those I believe meet the OIG's criteria for investigation are all the examples of research misconduct in Appendices B through G of my letter. They include:

51 examples of falsified methods, data and/or results;

28 tables with errors and/or misrepresentations;

including all those published in the NEJM version;

16 figures with errors and/or misrepresentations,

including the only figure published in the NEJM version, which does not

match the HEI version printed before or the EHP version printed later;

11 examples of fabricated methods, data and/or results;

11 examples of inappropriate authorship (at least 2 guests and 9 ghosts);

3 examples of unethical treatment that affected all cases and controls;

3 examples of plagiarism, reprinting work of both themselves and others

without quotation, reference or permission; and

2 examples of redundant publication of the same results

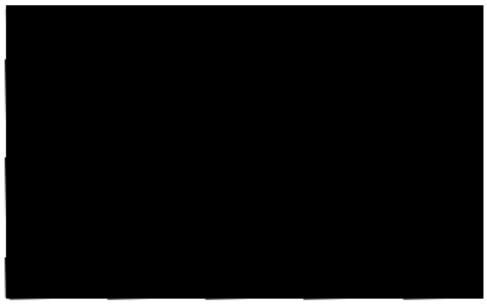
including the longest "original article" ever published by EHP at 41 pages,

over 90% of which, including all its figures and tables, is copied without quotes,

reference or explanation from the HEI version published two years earlier.

This still leaves 61 deviations from the norms of scientific research in Appendix A that I believe reflect a "loss of scientific integrity" at both HEI [for doing them] and EPA [for accepting them without question] but which do not in my lay opinion rise to the level of criminality.

I look forward to hearing from you soon. Thank you for your consideration.



[redacted]

From: Sullivan, Patrick F.
Sent: Wednesday, May 29, 2013 9:54 AM
To: [redacted]
Cc:
Subject: FW: Questions about your letter, Re: EPA OIG Hotline 2013-159

One more email from [redacted]

[redacted]

Sent: Thursday, May 23, 2013 5:17 PM
To: Sullivan, Patrick F.
Subject: Fwd: Questions about your letter, Re: EPA OIG Hotline 2013-159

Here is my email of 5/23 about [redacted] conflicts in this matter and [redacted] unresponsive reply.

[redacted]

[redacted]

Sent: Thursday, May 23, 2013 10:28 AM
To: [redacted]
Subject: Questions abeut your letter, Re: EPA OIG Hotline 2013-159

[redacted]

The letter you sent me last week says you forwarded "information about my complaint" to the "Deputy Director for the US EPA Science Advisory Board."

Can you please tell me

a) if this Deputy Director is [redacted] why did OIG choose to send my complaint to him?

He is the highest level person still at SAB [after [redacted] left] who refused to investigate or even respond to the written allegations I sent him last year. Doesn't this make him a potential subject of the investigation and therefore not an appropriate person for OIG to ask to lead the investigation? I beg OIG to reconsider.

He still refuses to answer any of my specific questions of the SAB's procedures and insisted in emails on 5/20 that I speak instead only with his new boss, [redacted] I did so on 5/21 and to his credit, he agreed to initiate a new investigation within SAB, but it is not clear if this will be separate from or take over [redacted] investigation of complaint #2013-159. Please clarify OIG's intent -- who is supposed to lead this investigation at SAB, and why did you not send it also or instead to [redacted] the senior counsel for ethics in the ethics office at OGC?

Another reason for OIG to investigate [redacted] is that he lied to [redacted] about the status of my complaint, telling him that all my allegations had been investigated and dismissed by OIG and that there was therefore no problem with appointing [redacted]

It is hard to imagine from whom [redacted] could have gotten this mis-information about my case since the only document you say OIG ever released about my original case, #2012-141, was a closure letter in December that made clear no investigation had been initiated by OIG. Would you have a sent a copy to [redacted] at the time? Could it possibly have misled him into thinking that OIG had in fact completed an investigation?

b) exactly what information from me did you forward to [redacted] last week as part of 2013-159? Was it just a copy of my original complaint 2012-141, or also the emails I sent [redacted] and the OIG [cc'd to you] with additional documentation?

Given that your closure letter to me was lost in the changeover to the new email system, I'm concerned that all my other emails to you were probably lost as well, and if so, I would like to resubmit them.

Thank you.

[redacted]

On Thu, May 23, 2013 at 10:54 AM, [redacted] wrote:

The Hotline is closed with the OIG and the letter states to whom your complaint was sent.

Special Agen[redacted]
Desk Officer for the OIG Hotline
US EPA, OIG, Office of Investigations HQ
1200 Pennsylvania Ave NW Mailcode 2431T
Washington, DC 20460
[redacted]

Hotline - 202/566-2476 or 888/546-8740

Hotline Fax 202/566-2599

[redacted]

From: [redacted]
Sent: Thursday, May 16, 2013 3:08 PM
To: [redacted]
Subject: RE: EPA OIG Hotline 2013-159

I do not have it. We converted from Lotus Notes to Outlook and my old emails were purged in January 2013. [redacted]

Special Agent [redacted]
Desk Officer for the OIG Hotline
US EPA, OIG, Office of Investigations HQ
1200 Pennsylvania Ave NW Mailcode 2431T
Washington, DC 20460

Hotline - 202/566-2476 or 888/546-8740
Hotline Fax 202/566-2599

[redacted]

Sent: Thursday, May 16, 2013 2:59 PM
To: [redacted]
Subject: Re: EPA OIG Hotline 2013-159

i got this fine, but i can't find the email you say you sent me last december closing my original complaint. can you please resend that to me?

thanks

[redacted]

On Thu, May 16, 2013 at 1:40 PM, [redacted] wrote:

Please let me know that you received this. Thanks [redacted]

Special Agent [redacted]
Desk Officer for the OIG Hotline
US EPA, OIG, Office of Investigations HQ
1200 Pennsylvania Ave NW Mailcode 2431T
Washington, DC 20460

Hotline - 202/566-2476 or 888/546-8740

Hotline Fax 202/566-2599

another individual to any person or organization. EPA employees who willfully release protected information, without authority, may be guilty of a misdemeanor and fined up to $5,000. In addition, any employee violating the Privacy Act or EPA regulations is subject to disciplinary action, which may result in dismissal.

www.COconundra.info

[redacted]

From: [redacted]
Sent: Wednesday, March 18, 2015 11:03 AM
To: [redacted]
Subject: RE: OIG FOIA request re case 2014-152 // 2015-086

Thank you for your email. Please review the EPA OIG website for FOIA requests information at http://www.epa.gov/oig/contact.html#FOIA.

Additionally the email for EPA OIG FOIA requests is: OIG_FOIA@epa.gov

When you file online you will receive an acknowledgment. I cannot file a FOIA request for you. Moreover, FOIA are not handled by the Hotline [redacted]

Special Agent Clay M[redacted]
Desk Officer for the OIG Hotline
US EPA. OIG, Office of Investigations HQ
1200 Pennsylvania Ave NW Mailcode 2431T
Washington, DC 20460
Voice - [redacted]

Hotline - 202-566-2476 or 888-546-8740
Hotline Fax 202-566-2599 Web Address oig_hotline@epa.gov

[redacted]

Sent: Monday, March 16, 2015 1:49 PM
To: OIG FOIA
Cc: [redacted]
Subject: Re: OIG FOIA request re case 2014-152 // 2015-086

Can you please tell me the status of the FOIA request below from JAn 15, 2015, which your office has now had for 60 days but still not even acknowledged?

Thanks,
[redacted]

On Thu, Jan 15, 2015 at 10:04 PM [redacted] wrote:

Please accept this FOIA request for all reports, memos and correspondence related to the EPA OIG's review of case 2014-152, which was renumbered as 2015-086 prior to being closed.

In his closure letter to me of 1/15/2015, [redacted] mentions that the OIG is forwarding its report on this matter to EPA's Francesca Grifo. This OIG report--which is presumably dated sometime in either December 2014 or January 2015-- is the primary document I am seeking in this request. Please also include any correspondence between OIG and EPA staff about this matter, and any notes or minutes from their meeting on December 19, 2014.

Because I am seeking this information for non-commercial academic research that is in the public interest--concerning the scientific basis of EPA's CO air quality standards--I request that your office waive any fees.

Thank you for your consideration.

[redacted]

[redacted]

From: [redacted]
Sent: Thursday, January 15, 2015 5:49 PM
To: [redacted]
Subject: RE: EPA OIG Hotline 2015-086

There is a link on epa.gov in the OIG section for submitting FOIA. Make sure you include the Hotline #

Special Agent [redacted]
Desk Officer for the OIG Hotline
US EPA, OIG, Office of Investigations HQ
1200 Pennsylvania Ave NW Mailcode 2431T
Washington, DC 20460
Voice - [redacted] Cell [redacted]

Hotline - 202-566-2476 or 888-546-8740
Hotline Fax 202-566-2599 Web Address oig_hotline@epa.gov

[redacted]

Sent: Thursday, January 15, 2015 5:47 PM
To: [redacted]
Subject: Re: EPA OIG Hotline 2015-086

ok. may i submit the foia request through you ?

On Thu, Jan 15, 2015 at 5:43 PM [redacted] wrote:

I combined the two hotlines into one for a referral to Ms. Grifo. The results of the review are now with 2015-086 and if you want these results it should be obtained through a FOIA to the OIG.

Special Agent [redacted]
Desk Officer for the OIG Hotline
US EPA, OIG, Office of Investigations HQ
1200 Pennsylvania Ave NW Mailcode 2431T
Washington, DC 20460
[redacted]

Hotline - 202-566-2476 or 888-546-8740

Hotline Fax 202-566-2599 Web Address oig_hotline@epa.gov

[redacted]

Sent: Thursday, January 15, 2015 5:39 PM
To: [redacted]
Subject: Re: EPA OIG Hotline 2015-086

Thank you for sending me this reply.

Can you please tell me why OIG assigned a new 2015 number--2015-086--to the complaint I filed in May of last year (2014-152),

and why the OIG combined this review with that of an unrelated and previously closed complaint, #2013-159?

Please also tell me if the OIG can release the report of its investigation into 2014-152 (the one your letter says has now been forwarded to Dr Grifo) and if so, whether I need to file a FOIA request for it.

I am curious to read why the OIG thought none of examples of contractor fraud I identified rose "to the level of criminal charges" and if any civil charges or other actions such as disbarment were considered before returning the case to Dr Grifo.

[redacted]

On Thu, Jan 15, 2015 at 4:08 PM, [redacted] wrote:

Please find attached a letter for this Hotline Closing. As the letter states it has been sent back to Ms. Grifo. [redacted]

Special Agent [redacted]
Desk Officer for the OIG Hotline
US EPA, OIG, Office of Investigations HQ
1200 Pennsylvania Ave NW Mailcode 2431T
Washington, DC 20460
[redacted]

Hotline - 202-566-2476 or 888-546-8740

Hotline Fax 202-566-2599 Web Address oig_hotline@epa.gov

[redacted]

From: [redacted]
Sent: Tuesday, September 09, 2014 4:09 PM
To: [redacted]
Subject: FW: Hotline complaint - Response from NEJM
Attachments: Response to [redacted]

Your email states that you have not received a response. Please find attached a response from the NEJM in case you have not received it. [redacted]

Special Agent [redacted]
Desk Officer for the OIG Hotline
US EPA, OIG, Office of Investigations HQ
1200 Pennsylvania Ave NW Mailcode 2431T
Washington, DC 20460
[redacted]
Hotline - 202-566-2476 or 888-546-8740
Hotline Fax 202-566-2599 Web Address oig_hotline@epa.gov

The NEW ENGLAND JOURNAL of MEDICINE

JEFFREY M. DRAZEN, M.D.
EDITOR-IN-CHIEF
DISTINGUISHED PARKER B. FRANCIS PROFESSOR OF MEDICINE
HARVARD MEDICAL SCHOOL

June 6, 2014

[redacted]

Dear [redacted]

We have received your e-mail requesting retraction of the article, "Short-Term Effects of Carbon Monoxide Exposure on the Exercise Performance of Subjects with Coronary Artery Disease," by E.N. Allred et al., which was published by the *New England Journal of Medicine* on November 23, 1989. We have read the letter you attached and the accompanying material. You provide no solid evidence of scientific or ethical misconduct; we therefore conclude that retraction is not warranted. If you have concerns about the validity of the article's conclusions, we suggest that you repeat the experiments, to the extent to which you believe this can be done ethically, and report your findings in a scientific journal for others to read and critique.

We now consider this matter closed.

Sincerely,

Jeffrey M. Drazen, M.D.

JMD:es

10 SHATTUCK STREET, BOSTON, MASSACHUSETTS 02115-6094
617.734.9800 · 1.800.445.6362 · 617.734.9864 FAX

[redacted]

From: [redacted]
Sent: Thursday, September 04, 2014 10:29 AM
To: [redacted]
Subject: FW: Missing attachment

Special Agent [redacted]
Desk Officer for the OIG Hotline
US EPA, OIG, Office of Investigations HQ
1200 Pennsylvania Ave NW Mailcode 2431T
Washington, DC 20460
[redacted]

Hotline - 202-566-2476 or 888-546-8740
Hotline Fax 202-566-2599 Web Address oig_hotline@epa.gov

From: [redacted]
Sent: Wednesday, September 03, 2014 9:19 AM
To: [redacted]
Subject: Missing attachment

[redacted] could send me the following for further review of your complaint? [redacted]

1) copies of the 'Attachments' referenced on page 15/18 of the letter [redacted] sent the NEJM? These attachments presumably provide support for the specific allegations of misconduct and are critical for evaluating the complaint.

Here's how the attachments are described in [redacted] letter to NEJM:

"Attachments (electronic versions only: click here to download via Dropbox)
A. Deviations from accepted norms of scientific research in Allred *et at.*
B. Deviations that meet definitions of scientific misconduct in Allred *et at.*
C. Misleading figures in Allred *et at.*
D. Misleading tables in Allred *et at.*
E. Sections of HEJM version copied from HEI version without attribution
F. Sections of EHP version copied from HEI version without attribution
G. Sections of HEI version deleted or changed in the EHP version

Special Agent [redacted]
Desk Officer for the OIG Hotline
US EPA, OIG, Office of Investigations HQ
1200 Pennsylvania Ave NW Mailcode 2431T

Washington, DC 20460
[redacted]

Hotline - 202-566-2476 or 888-546-8740
Hotline Fax 202-566-2599 Web Address oig_hotline@epa.gov

[redacted]

From: [redacted]
Sent: Friday, June 06, 2014 3:19 PM
To: Grifo, Francesca
Cc: Copper, Carolyn
Subject: Hotline 2014-152 [redacted]
Attachments: 2014-152 refferal.pdf

Official Referral fo[redacted] I am going to cc the AIG for OIG Office of Program Evaluation, Dr. Copper.[redacted]

Special Agent[redacted]
Desk Officer for the OIG Hotline
US EPA, OIG, Office of Investigations HQ
1200 Pennsylvania Ave NW Mailcode 2431T
Washington, DC 20460
[redacted]

Hotline - 202-566-2476 or 888-546-8740
Hotline Fax 202-566-0814 Web Address oig_hotline@epa.gov

[redacted]

From: [redacted]
Sent: Monday, June 02, 2014 6:09 PM
To: Grifo, Francesca
Subject: Re: Retraction request

Thanks for the reply. I will forward a formal referral to you on Wednesday. [redacted]

From: Grifo, Francesca
Sent: Monday, June 2, 2014 9:03:29 PM
[redacted]
Subject: RE: Retraction request

We can discuss next week – but we are happy to look into it if that works for you all. Confirm and we will reply back to [redacted]o that end.

Thanks
Francesca

Francesca T. Grifo, Ph. D.
Scientific Integrity Official
US EPA Office of the Science Advisor
202-564-1687
www.epa.gov/research/htm/scientific-integrity.htm

From: [redacted]
Sent: Wednesday, May 28, 2014 4:20 PM
To: Grifo, Francesca
Subject: FW: Retraction request

Is your office going to address this. Please advise. [redacted]

Special Agent [redacted]
Desk Officer for the OIG Hotline
US EPA, OIG, Office of Investigations HQ
1200 Pennsylvania Ave NW Mailcode 2431T
Washington, DC 20460
[redacted]

Hotline - 202-566-2476 or 888-546-8740
Hotline Fax 202-566-0814 Web Address oig_hotline@epa.gov

From: Sullivan, Patrick F.
Sent: Monday, May 19, 2014 8:36 PM
To: [redacted]
Cc: [redacted]
Subject: FW: Retraction request

Hotline.....
Patrick F. Sullivan
Assistant Inspector General for Investigations
EPA Office of Inspector General
Desk: (202) 566-0308
Cell: (571) 243-2195
Email: sullivan.patrick@epa.gov

From: Elkins, Arthur
Sent: Monday, May 19, 2014 7:26 PM
To: Sullivan, Patrick F.
Cc: Sheehan, Charles; Larsen, Alan
Subject: Fw: Retraction request

Patrick,

Please see the below hotline complaint. Please follow-up as appropriate.

Thanks.

Art

[redacted]

Sent: Monday, May 19, 2014 5:34:50 PM
To: Mccarthy, Gina; Elkins, Arthur; Grifo, Francesca; Costa, Dan
Subject: Retraction request

The attached letter is cc'd to you. It requests retraction of the Allred et al study of carbon monoxide that was published by the Health Effects Institute (1989), The New England Journal of Medicine (1989), and Environmental Health Perspectives (1991).

My request is based on extensive evidence of misconduct and other significant deviations from the norms of scientific research that I've documented in the letter and seven appendices.

Because EPA commissioned this study from HEI in 1983 and has been citing it as the primary basis for the CO National Ambient Air Quality Standards since 1991, including most recently in 2011, I hope you will review this evidence and reconsider EPA's faith in both the Allred study and HEI, which directed it.

If you find fault with my reanalysis, please let me know so that I may issue a correction and an apology. But if not--if you agree that this study is not of sufficient quality to be cited as the basis of EPA regulations--I hope EPA will stop citing it except as an example of the type of scientific misconduct for which federal contractors such as HEI should be disbarred. I trust EPA also will ban all the authors, including [redacted] from ever again being appointed to EPA's [redacted] or other any federal advisory committees.

Unlike the last time the evidence basis for the CO NAAQS was cast into doubt--back in the early 1980s when EPA's then most-cited CO researcher, Dr. Aronow, admitted fabricating drug testing data he'd submitted to FDA, I beg EPA not to commission even one more CO study. There are already over 25,000 references on CO in the medical literature that EPA has never reviewed, including over 5,000 published just since the last CO NAAQS review began in 2009.

Thank you for your consideration. I look forward to your reply.

[redacted]

[redacted]

From: [redacted]
Sent: Thursday, June 20, 2013 10:44 AM
To: [redacted]
Subject: [redacted]
Attachments: 2013-159 referral.pdf; 2013-159 letter.pdf

Rick and Jim, please find attached a letter to [redacted] from the AIGI regarding his hotline complaint to the OIG and the regarding the referral to the SAB. [redacted]

Special Agent [redacted]
Desk Officer for the OIG Hotline
US EPA, OIG, Office of Investigations HQ
1200 Pennsylvania Ave NW Mailcode 2431T
Washington, DC 20460
[redacted]

Hotline - 202/566-2476 or 888/546-8740
Hotline Fax 202/566-2599

[redacted]

From: [redacted]
Sent: Wednesday, September 10, 2014 9:42 AM
To: Copper, Carolyn
Cc: Grifo, Francesca
Subject: Fwd: Hotline complaint - Response from NEJM
Attachments: SPINO 1991JASA on PDM.pdf; ATT00001.htm

FYI. [redacted]

Sent from my iPhone

Begin forwarded message:

From: [redacted]
To: [redacted]
Subject: Re: FW: Hotline complaint - Response from NEJM

[redacted]

Thanks for sending me the NEJM letter, which I had seen. [Dr. Drazen actually wrote this on May 21, just 2 days after receiving my allegations, according to an email from [redacted] which I'll forward you separately.]

I should have been more clear that I was being very literal. When I wrote that I'd not received any reply to any of my over 150 allegations, I meant that no one at HEI, NEJM or EHP had specifically rebutted any of them, not that no one had sent me a reply.

The editor-in-chief of EHP also rejected my request for retraction without rebutting any of my allegations, as did HEI's board and staff.

I am appealing NEJM's decision to COPE, the Committee on Publication Ethics, and EHP's to the new interim editor-in-chief, Dr. Schroeder. I'll share with you any replies I receive.

Please give whoever is considering my case the attached article published by the HEI CO study's lead statistician [Pagano] and its programmer [Spino] in 1991, just a few months after EHP published the last version the CO study. This one is about a statistical method called "permutation distribution of the trimmed means" that Allred et al cites as their method in the HEI CO study.

Spino and Pagano make clear that Harvard did not have the computer power needed to compute p-values by the "permutation distribution" method for n=20 or 30 [Table 4 footnote]. So the HEI CO study could not possibly have used this method as the authors claim to analyze their n=62 results.

[redacted]

On Tue, Sep 9, 2014 at 4:09 PM, [redacted]

[redacted]

Your email states that you have not received a response. Please find attached a response from the NEJM in case you have not received it. [redacted]

Special Agent [redacted]
Desk Officer for the OIG Hotline
US EPA, OIG, Office of Investigations IIQ
1200 Pennsylvania Ave NW Mailcode 2431T
Washington, DC 20460
[redacted]
Hotline - 202-566-2476<tel:202-566-2476> or 888-546-8740<tel:888-546-8740>
Hotline Fax 202-566-2599<tel:202-566-2599> Web
Address oig_hotline@epa.gov<mailto:oig_hotline@epa.gov>

Note: Email attachment included the article cited below:

Cathie Spino and Marcello Pagano, *Efficient Calculation of the Permutation Distribution of Trimmed Means*, Journal of the American Statistical Association, Vol. 86, No. 415, pp. 729-739 (Sept. 1991)

[redacted]

From: [redacted]
Sent: [redacted] 2015 2:49 PM
To: [redacted]
Subject: FW: rumor of death in EPA's CO testing program

Special Agent [redacted]
Desk Officer for the OIG Hotline
US EPA, OIG, Office of Investigations HQ
1200 Pennsylvania Ave NW Mailcode 2431T
Washington, DC 20460
[redacted]

Hotline - 202-566-2476 or 888-546-8740
Hotline Fax 202-566-2599 Web Address oig_hotline@epa.gov

From: [redacted]
Sent: Thursday, January 15, 2015 2:18 PM
To: [redacted]
Subject: Re: rumor of death in EPA's CO testing program

thanks. obviously no hurry on this one.
[redacted]

On Thu, Jan 15, 2015 at 2:13 PM, [redacted] wrote:

> Will get back to you. Also still waiting on a final review of science misconduct. [redacted]

Special Agent [redacted]
Desk Officer for the OIG Hotline
US EPA, OIG, Office of Investigations HQ
1200 Pennsylvania Ave NW Mailcode 2431T
Washington, DC 20460
[redacted]

Hotline - 202-566-2476 or 888-546-8740

Hotline Fax 202-566-2599 Web Address oig_hotline@epa.gov

Hotline records are protected under the Privacy Act 5 U.S.C. § 552a. All EPA employees handling protected information have a legal and ethical obligation to hold that information in confidence and to actively protect it from improper uses. Except as specifically authorized, EPA employees shall not disclose, directly or indirectly the contents of any record about another individual to any person or organization. EPA employees who willfully release protected information, without authority, may be guilty of a misdemeanor and fined up to $5,000. In addition, any employee violating the Privacy Act or EPA regulations is subject to disciplinary action, which may result in dismissal.

From [redacted]
Sent: Thursday, January 15, 2015 2:11 PM
To: Grifo, Francesca; [redacted]
Subject: rumor of death in EPA's CO testing program

I spoke last week with a retired EPA employee from RTP who told me that a volunteer died of a heart attack while exercising on a treadmill in one of EPA's CO exposure studies there in the 1990s. He said this death was not publicly reported and that it was hushed up by EPA staff. This may explain why EPA stopped doing controlled exposure studies on CO in the 1990s, although they still do them for particulates, ozone and other pollutants.

He does not want to go public with this "rumor" so I told him I would talk to others who might be able to confirm it and he gave me a few names. Assuming I find someone who does, to whom should I report this death at EPA?

I tried the PHRE office, x2550, but [redacted] told me she is only responsible for approving human study protocols before they start or if problems arise while studies are underway and that she cannot act on --or even take--complaints about studies after they are finished.

If this is true, to whom should post-facto concerns about human subjects harmed in studies conducted by EPA staff be reported?

Thank you for your help.

[redacted]

El-Zoghbi, Christine

From: [redacted]
Sent: Friday, January 16, 2015 11:19 AM
To: [redacted]
Subject: FW: EPA OIG Hotline 2015-086
Attachments: 2015-086 referral combined.pdf; 2015-086 closeout letter.pdf

Hi [redacted]

Please enter into your hotline spreadsheet.

Thanks,
[redacted]

From: Copper, Carolyn
Sent: Thursday, January 15, 2015 4:32 PM
To: [redacted]
Subject: FW: EPA OIG Hotline 2015-086

For our hotline records. Thanks.

From: [redacted]
Sent: Thursday, January 15, 2015 4:07 PM
To: Grifo, Francesca [redacted]
Cc: Copper, Carolyn
Subject: EPA OIG Hotline 2015-086

Please find attached the referral to your office and the final closeout letter sent to [redacted] today. The [redacted] referral is still being reviewed by OIG Chemist [redacted]

Special Agent [redacted]
Desk Officer for the OIG Hotline
US EPA, OIG, Office of Investigations HQ
1200 Pennsylvania Ave NW Mailcode 2431T
Washington, DC 20460
[redacted]

Hotline - 202-566-2476 or 888-546-8740
Hotline Fax 202-566-2599 Web Address oig_hotline@epa.gov